**A Dissertation On**

# "TO EVALUATE THE EFFECT OF HOT AFFUSION BATH WITH EPSOM SALT ON PAIN MANAGEMENT IN OSTEOARTHRITIS OF KNEE"


Submitted by

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I, **Dr. B. PRABHAKARAN** solemnly declare that this dissertation entitled **"TO EVALUATE THE EFFECT OF HOT AFFUSION BATH WITH EPSOM SALT ON PAIN MANAGEMENT IN OSTEOARTHRITIS OF KNEE"** is a bonafide and genuine research work carried out by me at Government Yoga and Naturopathy Medical College and Hospital, Chennai from May 2018 - March 2019 under the guidance and supervision of **Dr. N. MANAVALAN**, N.D. (OSM), M.A (G.T), M.Sc. (Y&N), M. Phil, P.G.D.Y, P.G.D.H.M, P.G.D.H.H, Head of the Department - Department of Naturopathy. This dissertation is submitted to The Tamil Nadu Dr. M.G.R. Medical University, Chennai towards partial fulfillment of requirements for the award of M.D. Degree (Branch – I – Naturopathy) in Yoga and Naturopathy.

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The Institutional Ethical Committee of Government Yoga & Naturopathy Medical College and Hospital, Chennai reviewed and discussed the application for approval of "**TO EVALUATE THE EFFECT OF HOT AFFUSION BATH WITH EPSOM SALT ON PAIN MANAGEMENT IN OSTEOARTHRITIS OF KNEE**", project work submitted by **Dr. B. PRABHAKARAN,** 3rd year M. D. Naturopathy, Post graduate, Government Yoga and Naturopathy Medical College and Hospital, Chennai.

The proposal is **Approved**.

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## LIST OF ABBREVIATIONS

| | |
|---|---|
| **OA** | Osteo Arthritis |
| **HAB** | Hot Affusion Bath |
| **NSAIDS** | Non-Steroidal Anti-Inflammatory Drugs |
| **OAK** | Osteo Arthritis Knee |
| **OR** | Odd Ratio |
| **DALY** | Disability-Adjusted Life Year |
| **IHD** | Ischemic Heart Disease |
| **COPD** | Chronic Obstructive Pulmonary Disease |
| **IGFBP** | Insulin Like Growth Factor Binding Protein |
| **IGF-1** | Insulin Like Growth Factor 1 |
| **NOS** | Nitric Oxide Synthesis |
| **WOMAC** | Western Ontario And Mcmaster Universities Osteoarthritis Index |
| **K/L** | Kellgren- Lawrence |
| **MRI** | Magnetic Resonance Imaging Techniques |
| **ACL** | Anterior Cruciate Ligament |
| **IL-6,8,1,10** | Inter Leukin |
| **TNF** | Tumor Necrosis Factor |
| **MetS** | Metabolic Syndrome |
| **CI** | Confidence Interval |
| **ACR** | American College of Rheumatology |
| **VAS** | Visual Analogue Scale |

## ABSTRACT

**INTRODUCTION:**

Osteoarthritis(OA) is a wear and tear type arthritis. It has two primary processes; breakdown of cartilage in joints and abnormal bony growth formation called Osteophytes. It is a chronic degenerative disease that leads to structural alteration and biochemical changes of synovial membrane and joint capsule. WHO reports worldwide osteoarthritis affects 9.6% of men and 18% of women ages above 60 years and condition will be the fourth leading cause of disability by 2020

**OBJECTIVES:**. To assess the effectiveness of hot affusion bath with Epsom salt on knee related symptoms among patients with osteoarthritis of knee.

**STUDY DESIGN:** Quasi experimental study

**METHOD:** 40 study subjects belonging within the age group of 50-65 years, participated in the study. The study participants were instructed treated with Hot affusion bath with Epsom salt, thrice a week alternatively for three weeks. Assessment with WOMAC index and goniometer taken at baseline and after three weeks.

**RESULT:** The study showed the presence of significant reduction of knee related symptoms like pain, stiffness and improve range of motion.

**CONCLUSION :** The study proved that Hot affusion bath with Epsom salt is found to be effective in reduction of knee related symptoms like pain, stiffness among patients with osteoarthritis of knees.



**KEYWORDS:** hot affusion bath, Epsom salt, osteoarthritis of knee, range of motion, pain.

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## 1.0 INTRODUCTION:

Pain is defined as an unpleasant sensation occurring in varying degrees ofseverity as a consequence of injury, disease, or emotional disorder. It is more than unpleasant sensations. It is one of the major component part of our nervous system. Ultimately it is a perception, and a bodily state. Despite its unpleasantness, pain is acritical component of the body's defence system. It is part of a rapid warming and defence relay instructing the motor neurons of the central nervous system to minimize detected physical harm.

Osteoarthritis (OA) is a wear and tear type arthritis. It has two primary processes; breakdown of cartilage in joints and abnormal bony growth formation called Osteophytes. It is a chronic degenerative disease that leads to structural alteration and biochemical changes of synovial membrane and joint capsule. It is of multi-factorial aetiology[1].

The OA which has no cause is called as Primary OA[3]. Most people have this type and it is related to aging[1,2]. This type of OA can be present as localized, generalized or as erosive OA[3].Secondary OA caused by another disease or condition[4].

Pathological changes in the last stage of osteoarthritis include softening, ulceration and disintegration of the articular cartilage. Inflammation of synovial membrane involved[2,3]. Typical Clinical symptoms are pain, sometimes particularly after prolonged activity and weight-bearing: whereas stiffness after

inactivity[2]. Degenerative arthritis, usually affects the large weight-bearing joints, such as the hips knees, hands, feet and spine[1,2].

OA is the most common cause of disability in older adults[5]. The Global Burden of Disease 2010 states that Musculoskeletal Disorder accounts for 6.8% of DALYs Worldwide[6].

OA is associated both Modifiable and Non modifiable risk factors like obesity, lack of exercise, genetic predisposition, bone density, occupational injury, trauma and gender[7].

OA is common more in women than men, but the prevalence increases with age. 45% of Women over the age 65 years have symptoms while 70% women show radiological evidence of those over the age 65 years.

The risk factors which increase OA are age, female gender, increase body weight, occupational knee-bending posture, physical labour, hereditary factors and race, joint trauma, vitamin D deficiency and chondrocalcinosis[8]

Lack of exercise, obesity, lifestyle factors like Diabetes, Improper posture, trauma and inflammatory diseases aggravate it. The problem more complicated in Females in the perimenopausal period who gains weight and failure of oestrogen and become less ambulant and less active.

OA is the second most common rheumatological problem and most common joint disease with prevalence of 22% to 39% in India(Chopra A et al 2001)[9]. Other latest studies in India have reported a prevalence

of OA in India is reported to be in the range of 25.2 to 29.1% (Jayaseelan Venkatachalam et al 2018)[10] and 28.7% (Chandra Prakash Pal et al 2016)[11].

Osteoarthritis of the knee is a major cause of mobility impairment, particularly among females[2,5.] Before the age of 45, more men have osteoarthritis; after age 45, it is more common in women[12] .Average menopausal age in Indian women is 46.3 years as compared to 54 years in western countries[13, 14]. This predisposes Indian women to the risk of developing osteoarthritis at earlier age compared to their western counterparts. It could be due to loss of oestrogen especially close to menopausal years at this time[15, 16] Knee osteoarthritis" triggers a vicious cycle. The pain limits mobilityof knee joint and exercise, thus increasing body weight, diabetes etc. which in turn worsen the joint. So, multidisciplinary approach needed to treat osteoarthritis knee joint.

Permanent treatment options are away from the financial scope of our ordinary man, who tend to seek relief in NSAIDs (non-steroidal anti-inflammatory drugs) with resultant kidney injury and gastric ulcer disease. Deformities induced by the inflammatory processes make correction impossible when the disease is in the advanced stage. So, the rapid increase in prevalence of OA will lead to a situation wherein the physical disability arising due to the pain and loss of functional capacity reduces quality of life and increases the risk of morbidity associated will pose a major challenge to evolving low resource public health systems like in India and place a major burden on the economy of the country. There was limited evidence regarding depression, occupational and physical activities, and socio-demographic factors such as social class which is of important co-morbidities.

Naturopathy can be defined as a system of man building in harmony with nature cure on constructive principles on physical, mental, moral and spiritual planes of being and consist of non-invasive treatment modalities like diet therapy, fasting therapy, yoga therapy, mud therapy, hydrotherapy, massage, acupuncture, chromo therapy and magneto therapy.[17]

One of the naturopathy treatment is Hydrotherapy. The external or internal use of water with various temperatures, pressure, duration, and site and different modes of application in any of its forms (water, ice, steam) for health promotion or treatment of various diseases. It is one of the naturopathic treatment modality which was used widely in ancient cultures including India, Egypt, China, etc.

Hydrotherapy is one of the most important therapy in naturopathy, which has been used since Ancient times. It can be defined as a naturopathic modality that involves the use of water at different temperatures, pressures, states and modes of application for the treatment of various disorders. The physiological effects and therapeutic applications of hydrotherapy are diverse. Water used at various temperatures enhances blood flow, which is thought to help dissipate all chemicals and facilitate muscle relaxation[36]. In addition, the hydrostatic effect may relieve pain by reducing peripheral oedema and by dampening sympathetic nervous system activity[37]. Hipbaths, enemas, hot and cold fomentation, hot footbaths, spinal baths, steam baths, immersion baths, application of hot and cold packs as well as advanced modalities like whirlpool baths, sprays and jets are some of the various forms of hydrotherapy[38].

The first ultimate treatise on hydrotherapy explaining its techniques and effects was written by John Harvey Kellogg in 1900 entitled “Rational Hydrotherapy”[19].

Affusion according to webster revised dictionary “the act of pouring upon or sprinkling with a liquid as water upon a child in baptism”. According to Cyclopedia Affusion in medicine is the act of pouring water on the body as a curative means, as from a vessel. In Hot affusion bath water at 40-50 degree Celsius is poured on the affected part. This bath is useful in providing relief in the pain of muscles and joints.[3] Hot affusion bath (HAB) is given in material with facility to pour hot water on the body by a big jug or any nozzle.

Epsom salt is so named because it was discovered in EPSOM, England in the late 1600s. Its scientific name is magnesium sulfate and it has soothing benefits. It helps to maintain the proper functioning of muscles and nerves within the body, as well as maintain bone and joint strength. (NATIONAL HEALTH SCIENCES 2010). Scientists have learned that the best way to get magnesium into the body is topically through the skin[20]. A hot Epsom salt is the old New England home remedy for arthritis pain.

## 2.0 AIMS AND OBJECTIVE

**AIM:** To study the effectiveness of hot affusion bath with Epsom salt on pain management in chronic osteoarthritis of knees. It was hypothesized that the Hot Affusion bath with Epsom salt will help to reduce the pain in Osteoarthritis of Knee (OAK).

**OBJECTIVE:**

**PRIMARY OBJECTIVE:**

1. To study the effect of hot affusion bath with Epsom salt on relieving pain in osteoarthritis of knee. It was hypothesized that the Hot affusion bath with Epsom salt will help to reduce the pain in Osteoarthritis of Knee (OAK).

**SECONDARY OBJECTIVE:**

2. To study the effect of hot affusion bath with Epsom salt on range of motion in osteoarthritis of knee.

## 3.0 REVIEW OF LITERATURE:

### 3.1Osteoarthritis

Osteoarthritis is defined as a heterogeneous condition with focal areas of damage to the cartilage surfaces of synovial joints, and is associated with remodeling of the underlying bone, and mild synovitis.[42] It is the most common joint disorder.[39,40] It is the 6th -leading cause of disability worldwide. It is one of the Major cause of restricted activity.[41] It plays the leading cause of disability among the elderly[40] and also predicted to become the 4th leading cause of disability in 2020.One among the various causes for low quality of life.[41]

According to Global surveys about 100 million people suffer from Osteoarthritis.[43] Osteoarthritis is a slowly progressive degenerative disease which is characterized by gradual loss of articular cartilage.[44] In addition to damage to articular cartilage, there is also associated remodelling of subarticular bone, osteophyte formation, ligamentous laxity, weakening of periarticular muscles and in some cases, synovial inflammation. The pathologic features of Osteoarthritis comprise of joint space narrowing and osteophyte formation[44]. It is especially due to imbalance in the equilibrium between breakdown and repair of the joints.[45]

It can occur in any synovial joints of the body but the most common areas are the hands, knees, hips, and spine. It occurs either involving one joint or multiple joints at a time[46]. It affects all the structures of joint in a non-uniform 8 and focal manner[47].

The disease not only affect persons, physically but also psychologically and economically.[48] It has been the most common reason for total hip and total joint replacement.[39] Patients with OA are at a higher risk of death compared with the general population with an odds ratio (OR) of 1.54.[49]

### 3.2 Knee Osteoarthritis:

The knee joint is the largest and strongest joint in our body. Knee joint formed by the lower end of the femur, upper end of tibia and the patella. The ends of the three bones are enclosed with articular cartilage. Two wedge shaped pieces of cartilage called meniscus act as "shock absorbers" between your thighbone and shinbone. They are strong and rubbery to help cushion the joint and keep it stable. Knee joint is encircled by a thin lining called the synovial membrane. This membrane releases a fluid that lubricates the cartilage and reduces friction" [48] (Figure3.1)

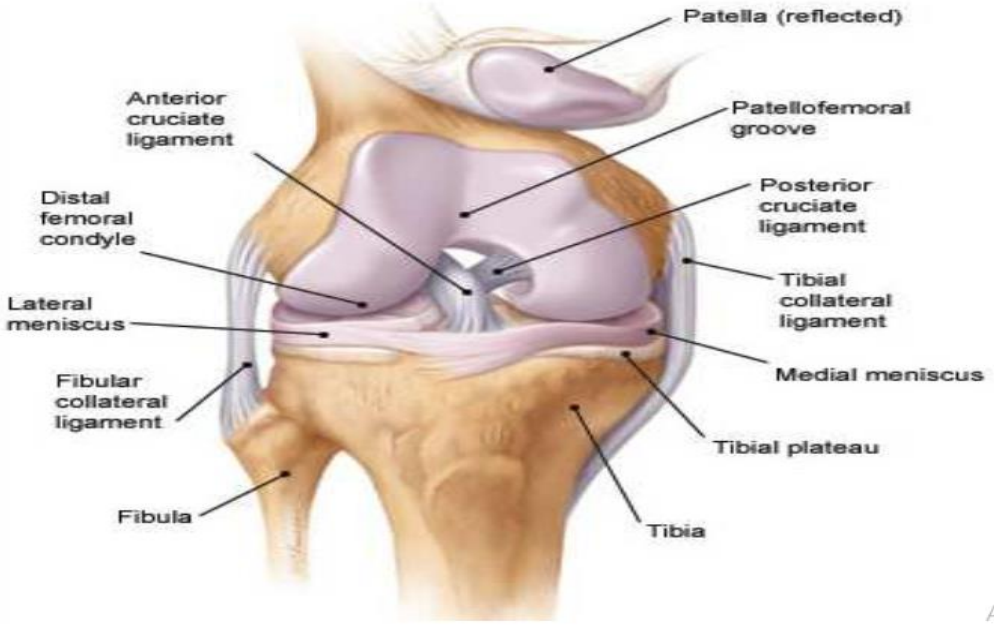


**Figure 3.1. Anatomy of knee joint**

The knee joint also comprise of three compartments 24 namely,

a. Medial compartment.

b. Lateral compartment.

c. Patello - femoral compartment

Inflammation of one or more of the structures listed above comprises Knee osteoarthritis.

### 3.3 Classification of Knee Osteoarthritis

Osteoarthritis is classified based on causes into primary and secondary. Primary or Idiopathic, when the underlying factors are not known. Secondary when certain conditions leads to osteoarthritis.

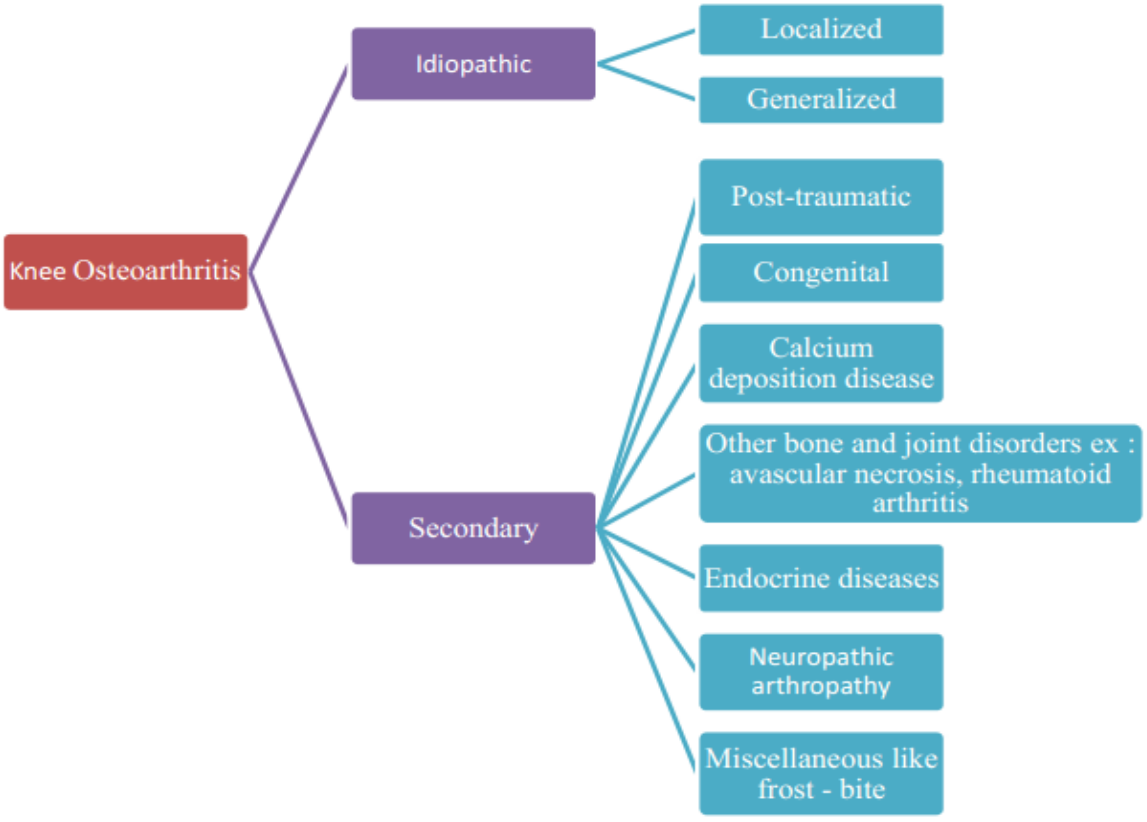


**Figure 3.2: Classification of Knee Osteoarthritis**

### 3.4 Global scenario

According to global burden of diseases 2010 study, Knee OA was ranked as the 11th highest contributor to global disability and 38th highest in DALYs[50].

Liu Y et al studied the prevalence of symptomatic knee osteoarthritis among people more than 40 years lived in rural China during the study period. The study reported that the overall prevalence of symptomatic knee OA was33%.[25]Allen KD and Golightly YM in their study found out that among a cohort of adults aged 56 to 84 years residing in Malmo, Sweden, the prevalence of radiographic and symptomatic knee OA were 25.4% and 15.4%, respectively[51].

Cho HJ from Korea reported that the prevalence of radiographic knee OA was 38% more than 60 years of age[52].

Ho Pham et al in his study "Prevalence of Radiographic Osteoarthritis of the Knee and Its Relationship to Self- Reported Pain" reported that the point prevalence of radiographic knee OA was 34.2% among the population more than 40 years residing in Ho Chi Minh City of Vietnam[53]Kim I et al from Korea reported that the prevalence of symptomatic knee Osteoarthritis among Korean elderly was 24.2%[54].

### 3.4.2. Indian Scenario

Epidemiological profile of osteoarthritis in India is unclear. It was estimated that the prevalence would fall between 22% to 39% in India[42]. Community survey data reported the prevalence to be in the range of 17% to 60.6%55. Pal CP et al reported that the prevalence of Knee OA in India was 28.7%.[56] In the year 2018,

Venkatachalam J from Tamil Nadu reported that the prevalence of knee arthritis was 27.1% in a rural area of Kancheepuram[10].

In 2007 Srivatsava reported that the elderly (people above the age of 60 years) comprise 7.5 percent of India's total population, and one of the health priorities of the country is to make health care available and easily accessible to them[6].

The epidemiological data on health problems in elderly reported that in 2007 as follows: Poor Vision (45.4%), Hypertension ( 38.2%), Arthritis ( 36.1%), Bowel complaints ( 31.6%), Depression ( 23.6%), Difficulty in Hearing ( 20.5%), Weight Loss (19.6%), Anaemia (16.8%), Urinary complaints (13.4%), Diabetes (13.3%), Fall ( 8.7%), IHD ( 7.7%), Asthma ( 6.6%), COPD ( 4.8%), and Tuberculosis (3.1%) were the common health problems highlighted by the study.[6]

**3.5 Pathophysiology**

Osteoarthritis is the product of interplay between local and systematic factors[49]. Repetitive mechanical injury had been proposed to be the critical signal that initiates all the changes in osteoarthritis[43]. The pathophysiology of osteoarthritis included an integrated role of all the structures of joint namely, cartilage, bones and synovial tissue. Initially, it was thought the entire pathogenesis was related to cartilage alone. Later it was found out that bone and synovial tissue also play their part[57].

**a. Pathological changes at the level of cartilage**

Since the cartilages are both a non-vascularised and non-neural structure. The Non-vascularised nature restricts supply of nutrients and oxygen to the chondrocytes[57]. Chondrocytes consist of single cellular component of adult hyaline

cartilage. These terminally differentiated cells maintain the cartilage matrix under normal conditions of low turnover[44].

Biomechanical, genetic and biochemical factors contribute to the OA lesion in cartilage by disrupting the chondrocyte-matrix associations and altering metabolic response in cartilages.[44,57]

Characteristics of osteoarthritic (OA) chondrocytes include the following:

Increased functions

1. Type II collagen and aggrecan synthesis (early OA)
2. Cell proliferation (chondron formation)
3. Catabolic cytokine production Proteinases (Matrix Metallo Proteinases (MMP), aggrecanases, Plasminogen activator, cathepsins)
4. Interleukin-1 receptor type I
5. IGFBP-3 Apoptosis, (IGFBP – Insulin Like Growth Factor Binding Protein)
6. Nitric Oxide Synthase (NOS), cyclooxygenase 2 (COX-2) Expression of collagen types VI, III, X, IIA

Decreased functions

1. Type II collagen and aggrecan synthesis (late OA)
2. IL-1 receptor antagonist
3. Response to insulin-like growth factor 1 (IGF-1)

At the initial stages the chondrocytes tend to repair the damage. But the process fails and leads to imbalance in favour of degradation. Various processes like increased synthesis of tissue-destructive proteinases (matrix metalloproteinases and

aggrecanases) increased apoptotic death of chondrocytes and inadequate synthesis of components of the extracellular matrix. This leads to production of matrix that is unable to with stand normal mechanical stresses. The above disrupts normal balance in favour of degradation. Failure of the repair process of damaged cartilage due to biomechanical and biochemical changes in the joint[45].

**b. Pathological changes in synovial tissue**

Following the damage to cartilage, cartilage debris and catabolic mediators enter the synovial cavity. Synovial macrophages produce catabolic and pro-inflammatory mediators and inflammation which starts negatively affecting the balance of cartilage matrix degradation and repair. The above not only initiates synovial inflammation but also drives it to higher levels. Synovial inflammation corresponds to joint pain and joint swelling[57].

c. **Pathological changes in bone**

It was proposed that sub-chondral bone changes could initiate osteoarthritis[57]. The characteristic changes regarding osteoarthritis at the bone level were,

a. Osteophyte formation.

b. Bone remodelling.

c. Subchondral sclerosis.

d. Attrition

**3.7 Signs and symptoms**

Clinically, Osteoarthritis include symptoms like

a. Joint pain related to use

b. Short-lasting inactivity

c. Stiffness of joints

d. Pain on movements

e. Restricted range of movements

f. Cracking of joints – crepitus

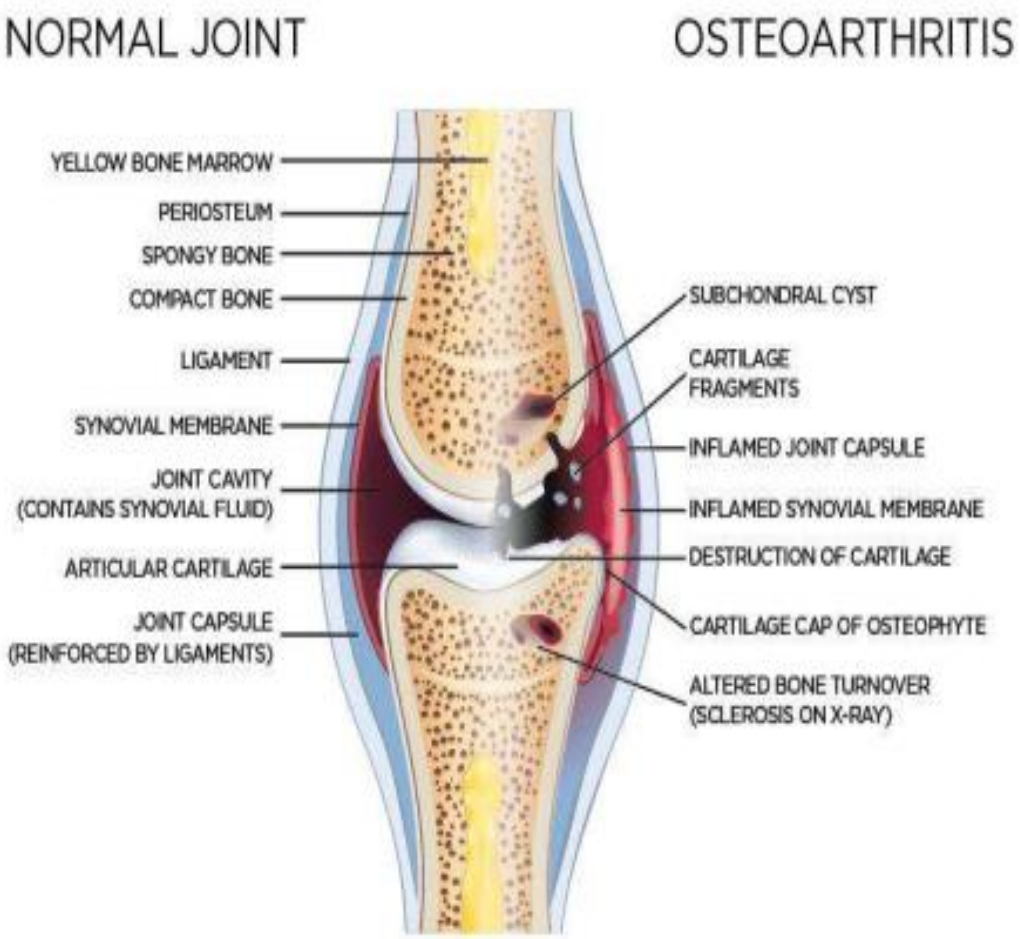


**Figure 3.3 showing normal and Osteoarthritic Joint**

**Knee pain**

Pain due to osteoarthritis is important because osteoarthritis is the biggest cause of high rate regional joint pain in older people[39]. It is also the symptom which drives people to seek medical care[40]. Pain perception in knee osteoarthritis is a complex process. The traditional thought was that the tissue damage leads to a nociceptive sensory input to the receptors which was then expressed as pain. Researches had linked knee pain not only to the local pathology but also to other non-OA variables like psychosocial factors, education, economic statusetc[40].

**3.8 Evaluating symptomatology and functions**

Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) is the instrument widely used to evaluate symptomatology and functions in patients with hip and knee Osteoarthritis[58].It was to evaluate the health status of the person suffering from OA and how the health status changes with clinical interventions[58] . WOMAC is a disease-specific, self-administered questionnaire and it covers three dimensions namely pain, stiffness and physical function[58].

1. Pain – 5 items
2. Stiffness - 2 items
3. Physical function – 17 items

**WOMAC Questionnaire Content**

**3.8.1 Pain Subscale**:

1. Walking on flat surface
2. Going up/down stairs
3. At night

4. Sitting/lying

5. Standing upright

### 3.8.2 Stiffness Subscale

6. Morning stiffness

7. Stiffness occurring later in the day

### 3.8.3 Physical Function Subscale

8. Descending stairs

9. Ascending stairs

10. Getting out of chair

11. Remaining in standing position

12. Bending

13. Walking on flat surface

14. In/out of car

15. Shopping

16. Socks/stockings on

17. Getting out of bed

18. Socks/stockings off

19. Lying in bed

20. In/out bath

21. Sitting

22. Toileting

23. Heavy domestic duties

24. Light domestic duties

### 3.9 Diagnosis

The diagnosis of knee osteoarthritis is done by the combination between clinical, radio-graphical and pathological findings.

#### 3.9.1 Clinical diagnosis

Clinical OA is defined by features in the history and on examination[45]. "American College of Rheumatology radiological and clinical criteria for osteoarthritis of the knee" defined Knee arthritis with the following characteristics[58].

1. Knee pain for most days of previous month
2. Crepitus on active joint motion
3. Morning stiff ness lasting 30 min or less
4. Age 38 years or older
5. Bony enlargement of the knee on examination

Osteoarthritis is diagnosed, if 1,2,3,4 or 1,2,5 or 1,4,5 are present.

#### 3.9.2 Pathological

Osteoarthritis is characterised by focal areas of damage to the articular cartilage which are centred on load-bearing areas, other characteristics include new bone formation at the joint margins (osteophytosis), changes in the subchondral bone, variable degrees of mild synovitis, and thickening of the joint capsule[59] .

#### 3.9.3 Radiographical

Radiography was considered as the reference standard for diagnosis of osteoarthritis[58]. The following are the various ways by which osteoarthritis are diagnosed radiographically.

1. Kellgren-Lawrence (K/L) radiographic grading scheme and atlas[60].

2. Semi-quantitative examination of individual radiographic features, such as osteophytes and joint space narrowing[39]

3. The direct measurement of the inter-bone distance[39].

The most commonly used one is the Kellgren-Lawrence (K/L) radiographic grading scheme and atlas. The above grading, grades osteoarthritis into 5 levels(0 to 4)[59]

**Table 3.1: Grading of Osteoarthritis using Kellgren-Lawrence radiographic grading.[59,60]**

| Grade | Category | Features |
|---|---|---|
| **0** | None | No visible features of OA |
| **1** | Doubtful | Questionable osteophytes or questionable joint space narrowing |
| **2** | Minimal | Definite small osteophytes.<br>Minimal/mild joint space narrowing. |
| **3** | Moderate | Definite moderate osteophytes.<br>Joint space narrowing if at least 50%. |
| **4** | Severe | Severely impaired joint space.<br>Subchondral bone cyst and sclerosis. |

The presence of radiographic osteoarthritis is usually defined as a K-L grade of ≥ 2.16,

### 3.10 Risk factors

The risk factors are those factors which when present increases the probability of the disease. In case of osteoarthritis, risk factors have been identified leading to occurrence and progression of the disease.

#### 3.10.1 Risk factors contributing to the disease

Age

Sex

Physical activity

Body-mass index (including obesity)

Intense sport activities

Quadriceps strength

Bone density

Previous injury

Hormone replacement therapy (protective)

Vitamin D

Smoking (protective or deleterious)

Malalignment (including Varus and valgus)

Genetics

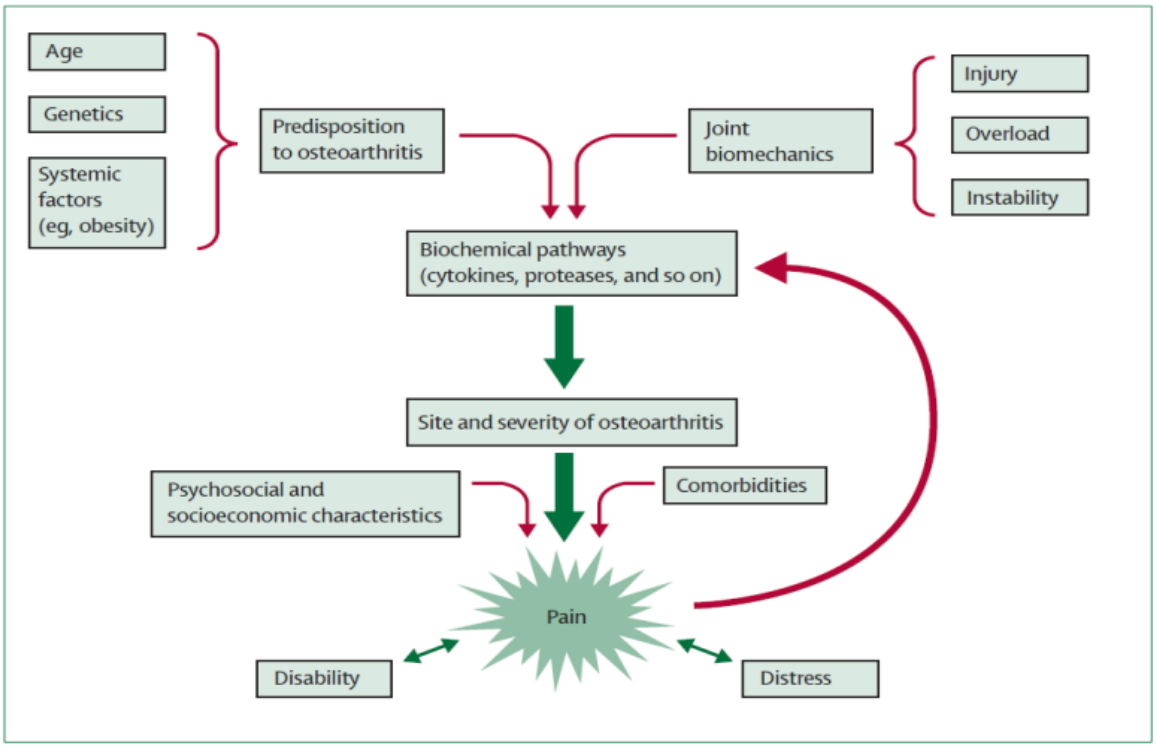




**Figure 3.4 showing relations between environmental and endogenous risk factors for joint damage, osteoarthritis and joint pain and their consequences**

### 3.10.2 Risk factors contributing to the progression of the disease

Age

Body-mass index (including obesity)

Vitamin D

Hormone replacement therapy (protective)

Malalignment (including varus and valgus)

Chronic joint effusion

Synovitis

Intense sport activities

Subchondral bone oedema on MRI

**Table 3.2 Risk factors and their possible causes of Osteoarthritis**

| RISK FACTOR | CONTRIBUTION |
|---|---|
| **Older age** | Incidence increases with age |
| **Female sex** | Prevalence is more in women. Obesity increases prevalence of osteoarthritis. |
| **Osteoporosis** | Associated with higher incidence and slower progression of OA |
| **Occupation** | Higher incidence of OA with repetitive squatting, kneeling, and bending |
| **Sports activities** | Increased risk of OA with high-impact contact, torsional loads, and overuse |
| **Previous trauma** | Increase in OA shown in athletes postinjury |
| **Muscle weakness or dysfunction** | Increases in OA with inactivity, poor training, and injury |
| **Proprioceptive deficit** | Increases OA with age, comorbid illness, and ACL injury |
| **Genetic factors** | Neither preventable or modifiable—variable expression |

## 3.11 Age and Osteoarthritis

Age is considered as one of the strongest risk factor not only for knee osteoarthritis but for all osteoarthritis.44 Both the prevalence and incidence of osteoarthritis increased with age. The above could be due to the consequence of

cumulative exposure to various risk factors. The biologic changes like cartilage thinning, weak muscle strength, poor proprioception and oxidative damage that occur with ageing, make a joint, less cop able with adversity[57]

Berenbaum F in his review "Osteoarthritis and cartilage" had stated that Osteoarthritis is a prototypic age-related disease. He also reported that at the cellular level senescence could be divided into replicative and secretory. Cell types like chondrocytes would not undergo replicative senescence rather undergo secretory senescence secreting pro-degradative mediators. This phenomenon increased with age.[63]

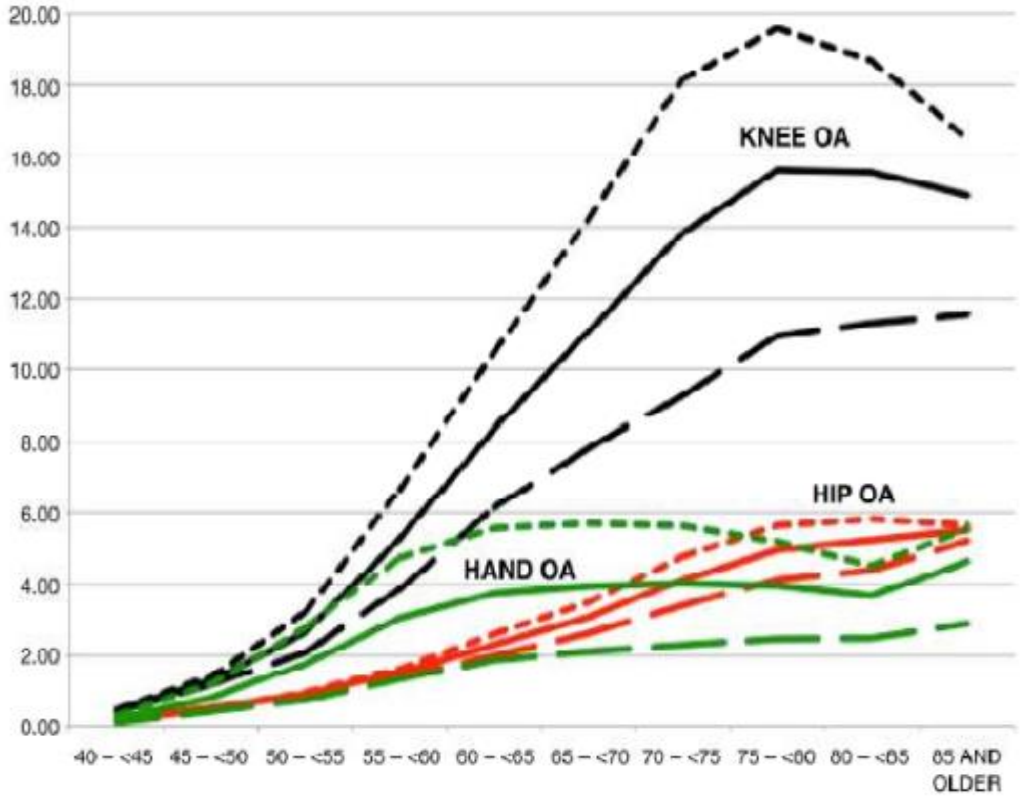


**Figure 3.5: Shows Age-specific incidence rates of knee osteoarthritis** (per 1000-person years) as indicated by the black line. (Solid line - all population; short dash line - women; long dash line – men)[67].

Dieppe PA et al., in his review stated that osteoarthritis was rare among people less than 40 years but most people after 70 years showed radiographical changes at least in one of their joints[46]. Cho HJ reported a similar finding in his study from Korea among elderly more than 60 years of age[52].

### 3.12 Sex and Osteoarthritis

The prevalence of osteoarthritis was found to be more in women than men. It was also recorded that women suffer from more severe form of osteoarthritis than men do[39].

Park JH et al., in a cross-sectional study among Korean elderly population reported that the prevalence of knee OA among males was 4.5% and females was 19%. The difference was statistically significant with p-value<0.05.41Similar results were reported by Cho HJ et al., from Korea. The study reported that females had 5.7 times increased risk of getting Knee OA than males.32Ho Pham et al also reported a similar pattern of prevalence among females and males.33In contrary Liu Y et al., reported no significant difference between sex in relation to the prevalence of symptomatic knee OA.

### 3.13 Occupation and Osteoarthritis

Occupations in which there was abnormal or exceeding lower extremity joint load were associated with osteoarthritis[52]. Occupational activities like kneeling, climbing, or squatting could increase the risk of Osteoarthritis.[65,66] Repetitive use of joints at work is associated with an increased risk of OA[67]. Workplaces offering job-switch accommodation, paid sick leave and disability

payment had lesser incidence of OAK than their counterparts[68].

Rossignol M in his study "Primary osteoarthritis of hip, knee, and hand in relation to occupational exposure" found out that certain occupations like female cleaners, women in clothing industry, male masons and other construction workers and agricultural male and female workers had increased risk of osteoarthritis than others. The study also reported that the incidence of OAK would be earlier, if one had a labour heavy job.[65]Kim I reported that manual occupation is a significant risk factor for OAK[54].

### 3.14 Obesity

Obesity is known as the potent risk factor of osteoarthritis of the knee joint[39]. It is a complex syndrome. In obesity there is an abnormal activation of neuroendocrine and pro-inflammatory pathways which leads to an altered control of food intake, fat expansion and metabolic changes. These activated white adipose tissues would increase the synthesis of pro-inflammatory cytokines, such as IL-6, IL-1, IL-8, TNF alpha, IL-18, but decreases the regulatory cytokines, such as IL-10.[70] Framingham osteoarthritis study reported that a weight reduction of 5.1 kgs or reduction in body mass index of 2 units reduced the incidence of knee osteoarthritis by 50%.[69]

Messier et al in their study pointed that this relationship between obesity and Knee osteoarthritis could be related to excess biomechanical joint stress.

### 3.15 Injury and surgery

Traumatic joint injury is a major risk factor for Osteoarthritis. In case of Knee joint injuries like meniscal damage, anterior cruciate ligament tear, direct

articular cartilage injury predispose to Knee osteoarthritis

Berenbaum F stated that “any abnormal mechanical stress applied on a joint (stretch, compression, shear stress, hydrostatic pressure) can be converted into activated intracellular signals in joint cells by mechanoreceptors present at the surface of joint cells (Integrins, Ion channels).

Signals may eventually lead to the over- expression of inflammatory soluble mediators such as prostaglandins, chemokines and cytokines when a certain threshold is reached”.[63]Hawamdeh ZM et al in his review quoted micro traumas and previous knee surgery as the risk factors for knee OA.[71]

### 3.16 Metabolic syndrome and Knee Osteoarthritis

Metabolic syndrome (MetS) is a common metabolic disorder due to increasing prevalence of obesity. It is characterised by obesity, hypertension, hyperlipidaemia and hyperglycaemia. It is associated with an increased risk of cardio-vascular disease. Xie DX et al reported that metabolic syndrome was significantly associated with the prevalence of Knee Osteoarthritis[60].

### 3.17 Diabetes mellitus

Plaza MN et al in the year 2013 reported that among the diabetics, 49% had OA while among the non – diabetics only 26.5% had OA.[72] In contrary Xie DX reported that hyperglycaemia though significantly associated in unadjusted model when adjusted to it was not significantly associated with OA.[60]

### 3.18 Hypertension

A meta-analysis by Zhang YM reported that hypertension was significantly associated with both radiographic and symptomatic knee OA. When

compared with non-hypertensives, hypertensives had two times more probability of suffering from radiographic knee OA and one and half times more probability of suffering from symptomatic knee OA.18Similar results were obtained by Kim I et al from Korea.[42]

In a hospital based study by Xie DX et al from China.[60]In contrary Plaze MN et al reported that hypertension had no influence over the prevalence of Osteoarthritis.[72]

**3.19Tobacco and osteoarthritis**

Men who have oak and smoke have greater cartilage loss and more severe pain than men who do not smoke, according to study result published in 2007 January Annals of the Rheumatic Diseases. The study led by a Mayo Clinic rheumatologist, examined the symptomatic knees of 159 men. The men were monitored for up to 30 months, out of 159 men, 19 were active smokers. The study revealed that the smokers were more than twice as likely to have significant cartilage loss than non-smokers.

**3.20 Studies related to joint pain in elderly**

Bartels EM, Lund H, Hagen KB, 2007, The coherent study conducted to compare the effectiveness and safety of aquatic-exercise interventions in the treatment of knee and hip osteoarthritis. Results show that there is a lack of high-quality studies in this area. In total, six trials (800 participants) were included. At the end of treatment for combined knee and hip osteoarthritis, there was a small-to-moderate effect on function (SMD 0.26, 95% confidence interval (CI) 0.11 to 0.42)

and a small-to-moderate effect on quality of life (SMD 0.32, 95% CI 0.03 to 0.61). A minor effect of a 3% absolute reduction (0.6 fewer points on a 0 to 20 scale) and 6.6% relative reduction from baseline was found for pain. Aquatic exercise appears to have some beneficial short-term effects for patients with hip and/or knee OA while no long-term effects have been documented. Based on this, one may consider using aquatic exercise as the first part of a longer exercise programme for osteoarthritis patients.[12]

Basar S, Uhlenhut K, Hogger. P. 2009 M. citrifolia is a tropical plant with a long tradition of medicinal use in Polynesia and tropical parts of eastern Asia and Australia. One of its favorite uses is the treatment of painful inflammatory conditions, such as arthritis. The analgesic activity of Non fruit puree on mice was investigated using the hot plate test. A 10% solution of freeze concentrated Noni fruit puree in the drinking water of mice reduced the pain sensitivity comparably to the central analgesic drug tramadol. This effect was only partly reversed by the application of the morphine antagonist naloxone. An alcohol extract of noni fruit puree also caused an inhibition of MMP-9 release from human monocytes after stimulation with LPS. This effect was comparable to hydrocortisone (10(-5) m). The findings suggest that preparations of noni fruits are effective in decreasing pain and joint destruction caused by arthritis. [13]

Men'shikova IV, Babyre VV. 2008;Pain in the knee joint is one of the commonest complaints for which people seek an advice of different medical specialists. The aim of this study was to elucidate the cause of pain in patients with the alleged diagnosis of "osteoarthrosis" and to develop the relevant diagnostic algorithm.

The study included 214 patients aged between 35 to 85 years with a pain level of at least 40 mm by the visual analog scale (VAS). Results of physical and X-ray examination provided indications for further studies that were performed by ultrasonographic (40.1%), arthroscopic (52.3%), and MRT (64.2%) techniques. One third of the patients were aged women with the body mass index > 40.1 and stage 3 osteoarthrosis (OA) in whom pain was attributable to primary osteoarthrosis. The remaining patients had pain of other origin. There was excellent (98.6%) agreement between MRT diagnosis and arthroscopic data on lesioned intra-articular structures, articular cartilage, and subchondral bone. Arthroscopy revealed traumatic and degenerative meniscal tear in 85% patients, injured anterior cruciate ligament in 8%, signs of synovitis in 52.6%, chondromalacia of the femoral condyle in 57.6%, and isolated pathology of patellofemoral articulation in 33% of the patients.[14]

The study conducted Thyberg I, Dahlström O, and Thyberg 2009 explored whether there are differences between women and men with regard to the reported level of fatigue, to explore the strength of the relations between fatigue and disease activity, pain, sleep disturbance, mental health, and activity limitation in early rheumatoid arthritis, and to explore the consistency of such findings. Analyses and comparisons of cross-sectional data. Two hundred and seventy-six patients, 191 women and 85 men, with early rheumatoid arthritis were included. Aliments were examined with respect to 28-joint count disease activity score, and disability variables reflecting pain, sleep disturbance, fatigue, mental health, and activity limitation, at follow-ups at 1, 2 and 3 years after diagnosis. Results show that Women reported somewhat more fatigue than men. Fatigue was closely and rather consistently related

to disease activity, pain and activity limitation, and also to mental health and sleep disturbance. Although this study does not permit conclusions to be drawn about causal directions, statistical relationships may be related to clinical conceptions about causation: when disease activity can be significantly reduced by pharmacological treatment this may have a positive effect on fatigue. [15]

In the 60th National Sample Survey Round in 2006 the results reported that, the aged persons proportion who cannot move and who are confined to their bed or home ranges from 77 per 1000 in urban areas to 84 per 1000 in rural areas Morbidity[7]. It is currently estimated that adults over 60 years makes 8 per cent of India's population and by 2021 that number will be increased to 137 million. India now has the second largest aged population in the world. The small-family norm means that fewer working, younger individuals are called upon to care for the increasing number of economically unproductive, elderly persons. In India 75% population living in the rural ares.[7]

In 2005 Shanthi G.S conducted the prospective study evaluated among 100 patients who are 60 years and above with falls a comprehensive geriatric assessment including detailed history of fall, ADL using Barthel index, underlying medical disorders, and medication history was elicited. Examination included assessment of all the system. Results showed that the 100 patients, Females contributed 68%. Among the causes for the falls, in people >70 years the common reasons prevailed was intrinsic causes. Among the medical conditions causing falls, musculoskeletal problems (72%) and visual defects (54%) were common. 46% had 3 or more risk factors for falls. Drug induced falls accounted for 42% of which 20%

were due to sedatives. Conclusion showed that Falls due to intrinsic causes such as joint pain and recurrent falls were common in people >70 years. Of the medical conditions predisposing to falls, musculoskeletal problems and visual defects were common.[9]

Mathur. A in 2007 reported that home health service, entailing home visits to detect health problems and also, a community-based health centre for the aged for educational and preventive activity will be initiated. This will be integrated with the National Rural Health Mission and an allocation made specifically for geriatric care. The Accredited Social Health Activist (ASHA) will be trained in geriatric care and the out-patient medical service, which serves as the base for home health service, will be enhanced. One of the aspects of home health service for the geriatrics is health education about the home remedies. [10]

Brosseau L, Yonge KA, Robinson V et.al conducted a Study in 2003 to determine the effectiveness of thermotherapy in the treatment of OA of the knee. The outcomes of interest were relief of pain, reduction of edema, and improvement of flexion or range of motion (ROM) and function. Two independent reviewers selected randomized and controlled clinical trials with participants with clinical and/or radiological confirmation of OA of the knee; and interventions using heat or cold therapy compared with standard treatment and/or placebo. The results shows that three randomized controlled trials, involving 179 patients, were included in this review. In one trial, administration of 20 minutes of ice massage, 5 days per week, for 3 weeks, compared to control demonstrated a clinically important benefit for knee OA on increasing quadriceps strength (29% relative difference) and another trail with hot

application. There was also a statistically significant improvement. Result showed that cold packs decreased knee edema. The thermotherapy reduces the pain. The study concluded that more well-designed studies with a standardized protocol and adequate number of subjects is needed to evaluate the effect of thermotherapy in the treatment of OA of the knee.[11]

Applying the heat by general or local method which produce the physiological change in the body such as vasodilatation and relaxation of muscles which produce the beneficial therapeutic effect of relieving the pain.

**3.21 Studies related to hot water application and joint pain**

In USA Aksan A, McGrath JJ, 2003 medical engineering department conducted study on heat-induced thermo mechanical response characteristics of collagenous tissues are quantified by means of in vitro experimentation with a representative model tissue (New Zealand white rabbit patellar tendon). Three distinct heat-induced thermomechanical response regimes (defined by the rate of deformation and the variation of material properties) are identified. Arrhenius damage integral representation of collagenous tissue thermal history is shown to be adequate in establishing the master response curves for quantification of thermomechanical response for modeling purposes. The trade-off between the improved kinematical stability and compromised mechanical stability of the heated collagenous tissue is shown to be the major challenge hindering the success of Sublative thermotherapies.[16]

Yildirim , N., FilizUlusoy, M., & Bodur, H. ( 2010) conducted a study to evaluate the effect of heat application on pain, stiffness, physical function and quality

of rheumatoid Arthritis the faculty of health sciences, Midwifery department, Cumhuriyet university, turkey. The intervention group received 20 minutes heat application every day for four weeks in addition to routine medication. It was found that hot application decrease the pain and disability of the patients with rheumatoid arthritis. Heat application was found to improve the sub dimensions of quality of life scores of physical function, pain and general health perception of patients.

Kirk, J.A., & Kersley, G.D. (2009) had studied the effectiveness of heat in the physical treatment of rheumatoid arthritis at Royal national 19 hospitals for rheumatic diseases. Hot packs were given for 20 minutes with temperatures approximately 45 degrees C at the beginning and at the end 41 degree C. Results showed that greater relief from pain and stiffness due to hot application.

Lehmann, JF., Warren, CG., & Scham, SM. ( 2009) conducted a study to assess the therapeutic effect of heat on rheumatoid arthritis. Patients received heat application to affected joint. Hot application had an effect on relieving the pain and stiffness. Hence, patients preferred for the heat therapy. The researcher concluded that superficial heat can be applied to chronic pain management.

Stanton, DE., Lazaro, R., & Macdermid, JC.(2008) reviewed the effectiveness of hot baths on rheumatoid arthritis at department of occupational therapy, Samuel Merritt college, California. The result addressed the physiological changes of hot application on blood flow, intramuscular temperature, subcutaneous temperature, and the influence of room temperature and age. The authors concluded that the heat bath procedure increased superficial blood flow and skin temperature.

Chou, R., Huffman, LH. ( 2007) conducted a meta-analysis of studies of non-pharmacological therapies for chronic pain in rheumatoid arthritis: a review of the evidence for an American pain society, American college of physicians. They found good evidence that the only non-pharmacological therapies with evidence to reduce pain or superficial heat application.

Parminder Kaur, et.al., (2007) conducted a study to assess the effect of 'moist heat application' on the intensity of joint pain among the geriatric population residing in Dadu Majra Colony, Chandigarh. The sample size consisted of 87 subjects, i.e. 43 in the experimental and 44 in the control group. Intensity of joint pain was assessed on the 1st and the 8th day of the intervention among both experimental and control groups. 'Moist heat' was applied at the joint twice a day for seven days in the experimental group. The results show that the intensity of joint pain and intake of painkiller was reduced significantly in the experimental group as compared to the control group.

Robinson, V., et al. (2007) conducted a review of research reports of studies at an institute of population health, university of Ottawa, Canada, on thermotherapy for treating rheumatoid arthritis to evaluate the effectiveness of thermotherapy application of objectives and subjective measures of disease activity in patients with RA. The review concluded that superficial moist heat can be used as palliative therapy.

Welch, V. Et al. (2007) the studies conducted to compare the ice and heat therapy in rehabilitation of rheumatoid arthritis patients. This study was conducted with 79 subjects to assess the effect of heat versus ice in relieving inflammation, pain

and mobility. They found that patients preferred heat therapy to ice. The study concluded that heat therapy can be used as palliative therapy, which can be applied at home as needed to relive pain.

Oosterveld, FG., & Rasker, JJ. (2006) reviewed the scientific basis for the treatment of arthritis pain with locally applied heat. They reviewed the experimental studies in healthy subjects and in patients. They found that the effect of heat on pain, stiffness of joints, grip strength and joint function in inflamed joints reported beneficial effects. They suggested that heat can be applied for chronic inflammation.

Preisinger, E., & quittan, M. (2006) reviewed the studies conducted to assess the effectiveness of thermotherapy at university of physical medicine and rehabilitation, Wein. Results showed that muscle spasm can be reduced by heat. Joint stiffness was decreased by heat application.

Kathleen L. Barman et al (2005) tested the efficacy of Treating joint Pain and Dysfunction Secondary to Osteoarthritis: Chiropractic Care Compared With The Moist Heat Alone. Two hundred fifty-two patients with joint pain secondary to OA were randomly assigned to either the treatment group (moist hot pack plus chiropractic care). Chiropractic care combined with heat is more effective than heat alone for treating OA-based joint pain.

Jeff Behar (2004) Hydrotherapy Additional measures to help ease the joint pain and stiffness include heat treatment. Simple hot water treatments are easy ways to soothe joint pain. To relieve stiffness and dull, penetrating pain, warm (not hot) compress applied directly to the affected area is the best option. Hot showers or baths

or heating pads may also help by improving flexibility, especially before exercise or other physical activity.

Brosseau L, Yonge KA, Robinson Vet. al (2003) conducted a randomized and controlled clinical trials to determine the effectiveness of thermotherapy in the treatment of OA of the joints. This study involving 179 patients, were included in this review. In one trial, administration of 20 minutes of ice massage, 5 days per week, for 3 weeks, compared to control demonstrated a clinically important benefit for the joints OA on increasing quadriceps strength (29% relative difference) and another trail with hot applications. There was also a statistically significant improvement. The result showed that cold packs decreased the joints edema. The thermotherapy reduces the pain. The study concluded that more well designed studies with a standardized protocol and adequate number of subjects is needed to evaluate the effect of thermotherapy in the treatment of OA on the joints.

Lloyd A, et al (2003) studied about the Cost-effectiveness of low-level therapy of heat wrap for joint pain. Total of 371 patients aged between 60 to 65 years with acute uncomplicated joint pain. They found that low level heat wrap gives relief both clinically meaningful in pain and reduction in disability. They suggested heat wrap therapy in place of oral analgesics in managing episodes of joint pain.

Lurie-Luke E, et al (1984) found that between 60 and 80% of the population in industrialized countries experience joint pain at some time in their lives. An exploratory work place study to investigate the perceived value of continuous low-level heat wrap therapy in manual workers was undertaken to investigate the benefits of a new form of continuous low-level heat wrap therapy available for the

symptomatic relief of acute low back pain in the workplace. The study results show that use of the heat wrap therapy significantly reduced pain intensity and impact of pain on everyday activities.

### 3.22 Studies related to effectiveness of epsom salt, hot application and Joint pain

The e news paper of Neha Arora in 2008 on personal health posted about the home Remedies for joint pain. Joint pain is a very common problem encountered by many people. As in a day-to-day life because of more work and less by aggravation of vata in the body. Home Remedies for Leg Pain and joint pain is a warm water bath of Epsom salt .Warm water bath of Epsom salt, which is rich in magnesium, is a good pain reliever. This is very helpful for arthritis.[17]

Health & Wellness › Common ailments 2007 the e article reported that. Add half-a-teaspoon of salt to a glass of warm water and rinse out your . Apply an ice bag to the side of the face where the pain is felt. Add one tablespoon of Epsom salts and an equal amount of ordinary salt to a pint of boiled water. A hot foot bath for about 20 minutes will often relieve the headache, joint pain, leg pain and other joint muscle ailments. Fill the tub with warm water and Epsom salts and just sink right in. This will relieve the pain related to muscle and joint injury.[19]

One in 2008 by Matthew Lewis, reported that there are dietary supplement of magnesium everyone can not use these effectively. Scientists have learned that the best way to get magnesium into the body is topically through the skin. A hot Epsom Salt bath is the old New England home remedy for arthritis pain. Just the heat of the bath itself is able to increase circulation and reduce swelling. The Epsom

Salt, then, adds properties which reduce pain and joint discomfort. To take an Epsom Salt bath, start by filling your bathtub with water that is as hot as you can tolerate. Then add two cups of Epsom Salt and dissolve them in the water. Stay in the bath for at least a half hour. Add hot water in order to keep the temperature very warm. Feel free to repeat this treatment often whenever required. Commercial lotions which contain Epsom Salt also available. They can be used to provide temporary, spot treatment on knees, legs, backs, and other body parts. You can massage this cream into your hands to help relieve the pain and reduce the swelling and stiffness of arthritic fingers. It can also be used to soothe achy, burning feet [20]

Adam Ramsay, (2014) 'Epsom salts, which are high in magnesium, can help to relieve joint pain, Christine Horner, nutritional therapist ' says at Margaret Hills Clinic the Epsom salt compress that helps patients with arthritis. 'Before bed, dissolve three teacups of Epsom salts into hot water' Soak a clean cloth in to hot water and make a compress, apply the compress to the joint for 10 to15 minutes, whilst slowly exercising the joints and muscles this will help to relieve the joint pain.

Fioravanti A, Tenti S, Giannitti C, Fortunati NA, Galeazzi M(2013) conducted a prospective randomized , single blind controlled trial to evaluate the effectiveness of Epsom salt compress in 60 outpatients with bilateral pain divided into two groupswith experiment group (n=30) treated with 12 daily generalized thermal baths with magnesium sulfate mineral water added to usual treatment and control group (n=30) continued regular outpatient care routine (exercise, NSAIDs and/or analgesics) for a duration of three months the study results confirmed that epsom salt compress had a beneficial effect in patients with joint OA.

Lawson Michelle (2010) According to MayoClinic.com, arthritis is a chronic inflammatory disorder that commonly affects the smaller joints in our feet and hands. The website also states that arthritis is more common among women than men and typically occurs between the ages of 40 and 60. The use of Epsom salt compress may reduce stiffness and pain due to arthritis.

Matthew Lewis at (2008) reported that there are dietary supplement of magnesium that everyone cannot use effectively. Scientists have learned that the best way to get magnesium in the body is topically through the skin. A hot Epsom Salt compress is the old New England home remedy for arthritis pain. Just the heat of the compress itself has been able to increase circulation and reduce swelling. It can also beused to soothe achy, burning feet.

The news paper of Neha Arora in (2008) on personal health posted about the home Remedies for joint pain, a very common problem encountered by many people. Home Remedies for Leg Pain and joint pain is a warm water compress of Epsom salt. Warm water compress of Epsom salt, which is rich in magnesium, is a good pain reliever. This is very helpful for arthritis.

Health & Wellness , Common ailments ( 2007) the article reported that 30 grams of Epsom salts added to one litter of boiling water (The temperature of the boiling water is as tolerated by the client ) creating a hot compress by dipping a clean washcloth in the boiling water, wringing it out, and applying for 20 minutes, twice a day for 7days to 10 days will often relieve the joint pain, leg pain and other joint muscle alignments. This will relieve the pain and reduce the swelling and stiffness of arthritic fingers. It can also be used to soothe achy, burning feet.

All the above literatures that have been reviewed clearly state that joint pain is very much prevalent worldwide and in India too. It mainly affects old age patients. Hot water treatments with Epsom salt has the property to relive pain as it has anti-inflammatory properties. Moist heat has proved to improve circulation and reduce pain. Hot water compress with Epsom salt combines the positive effect in relieving pain and has no adverse effects on health.

**3.23 Mechanism of action of Hot Affusion Bath and Epsom salt**

Buoyancy, immersion, resistance and temperature all play important roles. The pain relief may be due to the pressure and temperature of water on the skin, according to gate theory. Pain may be relieved due to the effect of pressure and temperature on nerve endings[80]. Water immersion induced an increase in methionine-encephalin plasma levels and conversely, suppressed plasma beta endorphin, corticotropin and prolactin levels.[81]

Soaking in an Epsom Salt bath is one of the most effective means of making the magnesium your body needs readily available. Epsom Salt also delivers sulfates, which medical research indicates are needed for the formation of brain tissue, joint proteins and the mucin proteins that line the walls of the digestive tract.

When the Epsom salt bath is taken it has been observed that the heat generated in the water helps increase the circulation of the blood and reduction of the swelling caused in arthritis. Magnesium in the Epsom salt is known to possess anti-inflammatory and anti-arthritic properties. Epsom salt can also be consumed as a part of the treatment.

However, all the symptoms for allodynia and hyperalgesia decreased after treatment with MgSO4. Moreover, this study reported increase in the concentration of glutamate in the synovial fluid in the arthritic condition of the inflamed knees. When the amount of magnesium is less in the body, this glutamate binds to the NMDA (N-methyl-o-aspartate) receptors which lead to allodynia and hyperalgesia. On treatment with Mg 2+ it was observed that these ions had preventive effect on the binding of glutamate to these receptors.

In addition to thus, the researchers reported that the deficiency of magnesium ions can lead to up regulation of the interleukins 1 and 6 (IL-1 and IL-6), cytokines and inflammation in the joints. It was reported in a study that increase in the IL-1 can lead to bone cancer in animal models by up regulating a factor known as p-NR1.

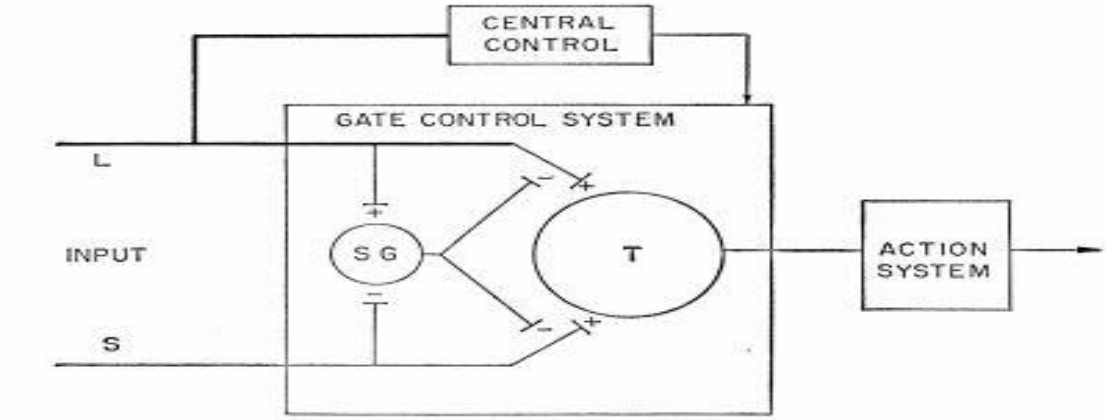


**Fig 3.6 Gate control theory of Pain mechanism**

*L large diameter fibers, S- small-diameter fibers. The fibers project to the substantia gelatinosa (SG)and first central transmission(T) cells. The inhibitory effect exerted by SG on the afferent fiber terminals is increased by activity in L fibers and decreased by activity in S fibers. The central control trigger is represented by a line running from the large-fiber system to the control mechanisms: these mechanism in turn, project back to the gate control system. +excitation, - inhibition*

**RATIONALE:**

Though both Hot Affusion bath and Epsom Salt used in relieving joint pain separately, but nowhere there is a study on Hot Affusion bath combined with Epsom salt in treating arthritis. So I am interested in this study to assess the efficacy of Hot affusion bath with Epsom salt.

**JUSTIFICATION**

The most common rheumatologic problem of the Aging people is the Osteoarthritis.

- Paucity of studies related to of osteoarthritis knee and the Epsom salt hot affusion bath.
- OA knee is often managed symptomatically with over-the-counter analgesics.
- The simple therapeutic measures which can be done in the home is not known to the people
- In order to institute the therapeutic measures for the needed people than the over counter analgesics.

## 4.0 MATERIALS AND METHODOLOGY:

### 4.1 Study area:

Government Yoga and Naturopathy Medical College, Hospital, Arumbakkam, Chennai-106.

### 4.2 Study Design

- Quasi experimental study.

### 4.3 Study Period

April 2018 to March 2019

### 4.4 Selection of study population

Total sample size N = 40

- Subjects are recruited from the people of Arignar Anna Hospital of Indian Medicine & Homeopathy, Chennai – 106.
- Subjects who satisfied the following inclusion & exclusion criteria were recruited for the study.

#### 4.4.1 Inclusion criteria

- Age: Above 50 years-65 years of age both male and female
- Patients having osteoarthritis of knee for minimum 6 months
- Persons below BMI 35
- Subjects diagnosed with primary osteoarthritis
- Orthopedic doctors diagnosed knee osteoarthritis patients (radiologically confirmed)
- Subjects who were willing to participate

- Informed written consent of the patients

### 4.4.2 Exclusion Criteria

- Congenital deformities
- Accidental Injury
- Varicose veins
- Chronic kidney failure (CKD)
- Seriously ill patients
- Rheumatoid arthritis
- Reactive arthritis
- Below 50 years and above 65 years of age
- Female who didn't attend menopause
- Old trauma of knee joint
- Subjects who have undergone total knee replacement in both the knees or any other knee surgeries

### 4.4.3. Withdrawal Criteria:

All subjects are free to withdraw from participation in the study at any time, for any reason, specified or unspecified, and without prejudice to further nature cure practices. Subjects who are withdrawn from the study will not be replaced.

## 4.5. Ethical Consideration:

Subjects who full fill inclusion criteria were appraised about the purpose of the study and their rights as research subjects. Informed consent form was administered in local language i.e., Tamil and English as well. Adequate time was

given to the participants to go through the information sheet and their queries were answered. Their rights to withdraw anytime from the study and the need for willingness to participate voluntarily in the study were explained. All the subjects expressed their willingness to participate in the study by giving a signed informed consent. (A sample information sheet and consent form is enclosed as Annexure-1) Ethical clearance was obtained from the Institutional Ethical Committee prior to the start of the study and the approval for the same was granted.

**4.6. Study setting:**

The study group was given Hot Affusion Bath with Epsom Salt for 15 minutes with cold compress to the head.

**4.6.1. Subjects:**

A total of 40 subjects were selected to participate in the study based upon the symptoms experienced. All subjects were subjected to Blood test and other examination to rule out Chronic kidney disease, Varicose vein . The subjects were briefed about the study and informed consent was obtained from them. This study was conducted within the per view of a larger study on the physiological effects of Hot affusion bath, and ethical approval was obtained from institutional ethical committee for the entire study.

After getting informed consent from the patient WOMAC Questionnaire is given to the patients to fill according to their symptoms. The temperature will be maintained by adding two mug of hot water more than $40^{O}$ C and temperature checked with water thermometer.

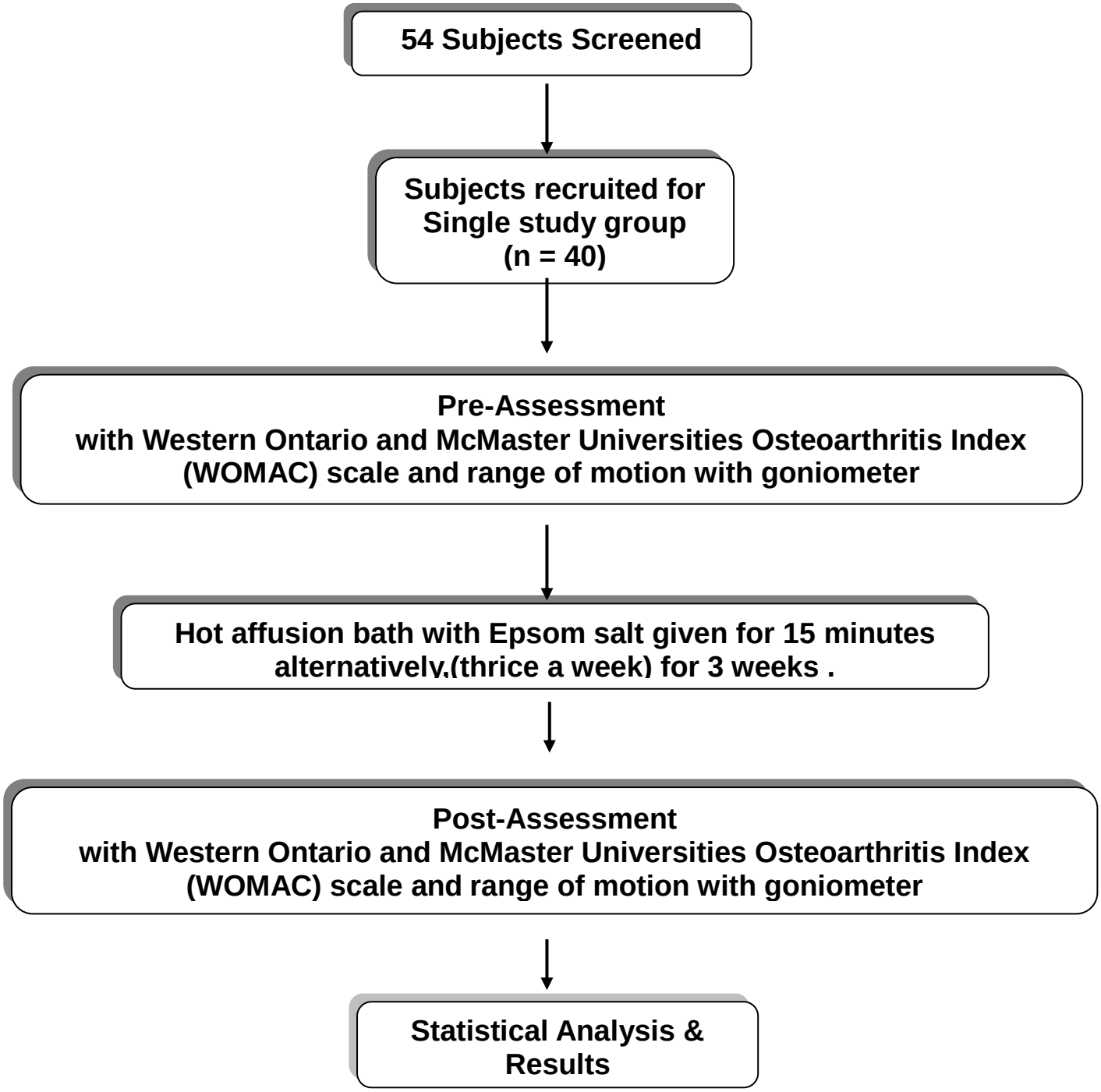


**Figure 4.1 Illustration of Study plan**

### 4.6.2 Written Informed Consent

Subjects who fulfilled the inclusion criteria were appraised about was sought from the Institutional Ethics Committee prior to the start of the study and the approval for the same was granted. The subjects were informed about the project and procedure, duration and effect of the treatment

**Fig 4.2 assessment sheet**

## 4.7 ASSESSMENTS

The baseline and post-intervention assessments consisted of :

1. WOMAC Questionnaire
2. RANGE OF MOTION.

In both legs, measuring degree of flexion and extension. pain, stiffness and physical function related symptoms were scored, pre and post data's collected for assessment.

### 4.7.1 Questionnaire

A validated semi structured questionnaire. Questionnaire for the present study was divided into 4 parts namely

- Socio demographic profile of the individuals
- Medical history
- History related to osteoarthritis knee joint
- WOMAC Index (Western Ontario and McMaster Universities Arthritis Index)

The questionnaire for the present study was developed based on WOMAC (the Western Ontario and McMaster Universities osteoarthritis index) it was used for rating of knee osteoarthritis used for accessing osteoarthritis knee joint. The questionnaire was modified according to the local need and validated with the help of expert.

**Table 4.1 Primary outcome variable Secondary outcome variables**

| Primary Outcome Variable | Secondary Outcome variable |
|---|---|
| WOMAC Questionnaire to assess | Range of Motion of Knee joints using Goniometer |
| Pain | Degree of Flexion |
| Stiffness | Degree of Extension in both the legs |
| Physical function | |

**Primary Outcome Variables**

**Western Ontario and McMasters Universities Osteoarthritis (WOMAC)**

The WOMAC evaluates 3 dimensions: pain, stiffness, and physical function with 5, 2, and 17 questions, respectively. The Likert version of the WOMAC is rated on an ordinal scale of 0 to 4, with lower scores indicating lower levels of

symptoms or physical disability. The questionnaire is self-administered and takes 5 to 10 minutes to complete. The WOMAC has been translated into German, Swedish, and Hebrew; a computerized version is available [73].

The WOMAC is intended to evaluate change in patient status following therapeutic intervention. Evaluation of therapeutic effectiveness relies on outcome measures that can accurately assess change. Specifically, the measure must be reliable[74] in order to ensure that true change is detected as opposed to measurement error.

In addition, construct and known group validity and responsiveness must be demonstrated before the tool can be used with confidence in a particular patient population. Reliability, validity, and responsiveness must be demonstrated for each new patient group.[75] This literature review summarizes the reliability, validity, and responsiveness of the WOMAC (subscales and global score) for the purpose of assisting clinicians and researchers in making decisions regarding the use of the WOMAC as an outcome measure.

Construct validity and responsiveness data were organized according to the joint being studied in each article (i.e. knee ). The results was based on the intervention in the study and miscellaneous. The miscellaneous category interventions, can be administered (i.e) exercise, manual and physical therapy and knee braces, can be given to evaluate the WOMAC scales. If it is needed. But not induced for this study.

**Theiler R,** et,al, 1999. study showed the superior responsiveness after knee surgery of pain and function of WOMAC compared to Leques enealgo functional

index with osteoarthritis of lower limbs.[76]

**Griffths,** et, al 1995 studied relative efficiency as a comparative study between WOMAC, AIMS AND HAQ instruments in evaluating the outcome of knee surgery.[77]

**Heck DA**, et, al 1998. explains patient outcome of pain, stiffness, physical function WOMAC scoring, after knee replacement surgery[78]

**SCHICK M, et, al** 1999. Study shows quality of life after total replacement of knee.[79]

#### 4.7.1.1 Pain

This theory is based on the work of Ronald Melzack (1965) and Wald (1972). They proposed the concept of functional gates through which all pain impulses pass.

Pain sensations originate mainly in two types of pain receptors: low threshold nociceptors that are connected to fast conducting a-fibers, and high-threshold nociceptors that conduct impulses through slower unmyelinated C-fibers. Central terminals of these sensory fibers enter the central nervous system (CNS) through the dorsal horn of the spinal cord, where they connect with spinal neurons via synaptic transmission. Neurons of superficial laminae I and deep laminae V project along the spinothalamic and spino-reticulo thalamic tracts to supraspinal sites such as the thalamus, parabrachial nucleus, and amygdala, where pain signals are further processed and sent on to higher cortical centers.[80]

#### 4.7.1.2 Stiffness

Due to degeneration and impairment of neuro muscular, less physical activity, muscular contraction gains leads to stiffness.

#### 4.7.1.3 Physical Function

Daily routine activities of human, affected due to symptoms of osteoarthritis, and performance of functional ability is measured and recorded by WOMAC questionnaire.

### 4.7.2 SECONDARY OUTCOME VARIABLES

It is a instrument widely used to measure the angles, particularly the Range Of motion. Measuring the limits, degrees of flexion and extension of the joints. A Calibrated protractor like device commonly with a $180^0$ range, is used to measure flexibility of musculoskeletal function, of various joints. In this study, this device have been used to record the measurements of physical function and muscle stiffness were assessed.

### 4.7.3 Range of Motion

#### 4.7.3.1 Definition of Range of Motion

Range of Motion is the measurement of movement around a specific joint or body part.

#### 4.7.3.2 Types of Range of Motion

There are three primary types of exercises specific to range of motion. **Passive range of motion** is typically practiced on a joint that is inactive. The physician may use this exercise on a client who is paralyzed or unable to mobilize a specific joint. This type of exercise can help prevent stiffness from occurring. During

this exercise the patient does not perform any movement, while the therapist stretches the patient's soft tissues.

**Active-assistive range of motion** exercises are more progressive, intended for the patient to perform movement around the joint, with some manual assistance from the physician, or from a strap or band. These exercises can often feel painful, and the muscles can feel weak. Increasing range of motion with these exercises should be a gradual advancement.

**Active range of motion** exercises are highly independent, performed solely by the patient The physical therapist's role may be simply to provide verbal cues.

### 4.7.4 MEASUREMENTS

To measure range of motion, physicians most commonly use a **goniometer**, which is an instrument that measures angle at a joint. Goniometers show degrees of an angle from zero to 180 or 360 degrees and are available in different shapes and sizes for the unique joints in the human body, when using a goniometer to measure knee flexion, the center of the tool will be at the side view of the knee joint, and the arms of the goniometer are aligned in the center of the long bones above and below the knee. As the knee is bent or flexed the movable arms provide a measure of the degree of movement. Other tools used to measure joint angle at extension and flexion are an **inclinometer**, which assists in measuring the spinal angle, or even a tape measure for various joints. In order to confirm that there is progress being made on increasing the range of motion in a joint, the physical therapist measures the joint angle prior to treatment, and continues to do so over time.

Normal ROM at the knee is considered to be 0 degrees of extension (completely straight knee joint) to 135 degrees of flexion (fully bent knee joint). Most functional activities require 0 to 120 degrees of motion at the knee. Common causes of decreased ROM include arthritis, knee surgery and knee injuries.

**Figure 4.3: Range of Motion**

Maintaining strength and flexibility in the muscles that control knee motion is crucial. The hamstrings are the primary knee flexors, and the quadriceps are the primary knee extensors.

## 4.8 INTERVENTION

Hot affusion bath with Epsom salt was given to the subjects alternatively thrice a week for 3 weeks. The subjects were asked to fill the questionnaire and Range of motion at baseline. Subjects were asked to come for thrice in a week alternatively for three weeks. After the third week, the subjects

were assessed for the intensity of pain, stiffness, physical functions and range of motion with the help of WOMAC Index scale and goniometry.

**PROCEDURE:**

- The subject is asked to were the dress above the knee.
- The subject is asked to sit in a wooden or plastic stool with both legs kept in a tub or bucket
- The cold compress is placed on the head of the subject as a safety measure.
- Then the hot water mixed with Epsom salt is poured on both the knees of the subject for 15 minutes in a circular motion.

**fig 4.4 Water thermometer**

**Fig 4.5 Treatment procedure**

**4.9 Statistical Analysis:**

Data expressed Mean ±SD and Median and IQR. Comparison of Mean in between the group was analyzed by paired t test and Wilcoxan sign Rank Test which is applicable. For Categorical variables Chi-square test is used. SPSS software version 23 was used for the analysis.

## 5.0 RESULTS

The present study was conducted to evaluate whether hot affusion water bath with Epsom salt had any influence in any of the outcome variable like pain and range of movements in Osteoarthritis of Knee (OAK). Results were compared within groups, where in data was extracted at baseline and post intervention for outcome variable.

The present study revealed hot affusion bath with Epsom salt reduced the pain score from 58.854 ± 34.375 and increased the range of movement from 80.63 ± 6.323 to 104.13 ± 7.586.

This shows that hot affusion bath with Epsom salt can be efficiently used as adjuvant treatment for people suffering from osteoarthritis of knees by relieving pain and improving range of movement.

## 5.1 Statistical analysis

| Sociodemographic Characteristics | Number of Participants(N) | Percentage(%) |
|---|---|---|
| AGE | | |
| 50-55 | 15 | 37.5 |
| 56-60 | 12 | 30.0 |
| 60-65 | 13 | 32.5 |
| GENDER | | |
| Male | 27 | 67.5 |
| Female | 17 | 32.5 |
| RELIGION | | |
| Hindu | 34 | 85 |
| Muslim | 5 | 12.5 |
| Christian | 1 | 2.2 |
| EDUCATION | | |
| Graduate | 9 | 22.5 |
| Post High School | 3 | 7.5 |
| High School | 10 | 25 |
| Middle School | 10 | 25 |
| Primary School | 5 | 12.5 |
| Illiterate | 3 | 7.5 |
| OCCUPATION | | |
| Professional | 1 | 2.5 |
| Semi-Professional | 3 | 7.5 |
| Clerical, shop owner | 11 | 27.5 |
| Skilled worker | 6 | 15 |
| Semiskilled worker | 13 | 32.5 |
| Unskilled worker | 1 | 2.5 |
| Unemployed | 5 | 12.5 |

**Table 5.1 Sociodemographic characteristics of the study population**

A total of 40 subjects participated and completed the intervention in the present study. Out of the 40 subjects 27 are Male and 13 were Female with Mean Age 57.73±4.563.

**LIFESTYLE FACTORS:**

Alcohol usage among study Participants:

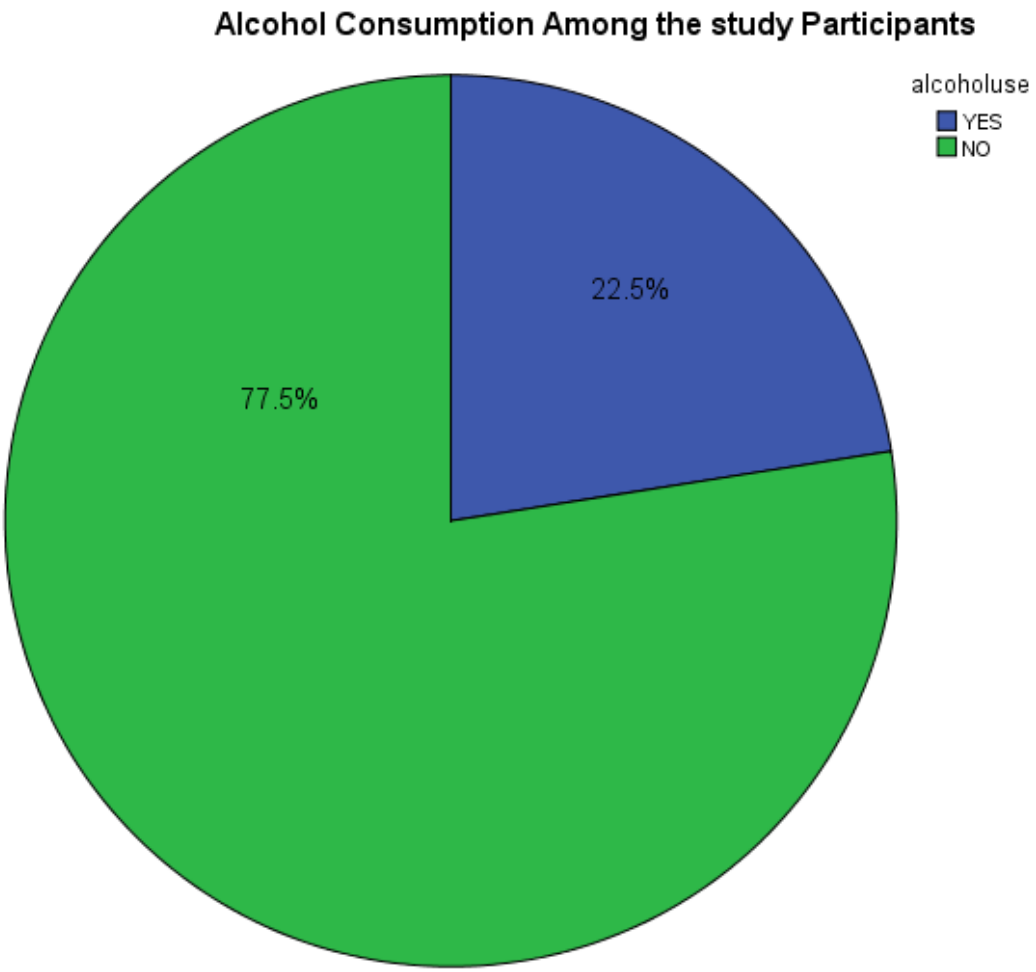


**FIGURE 5.1: Alcohol usage among study Participants**

Among the study population ,22.5% are having the habit of alcohol consumption while the remaining 77.5% doesn't have the habit

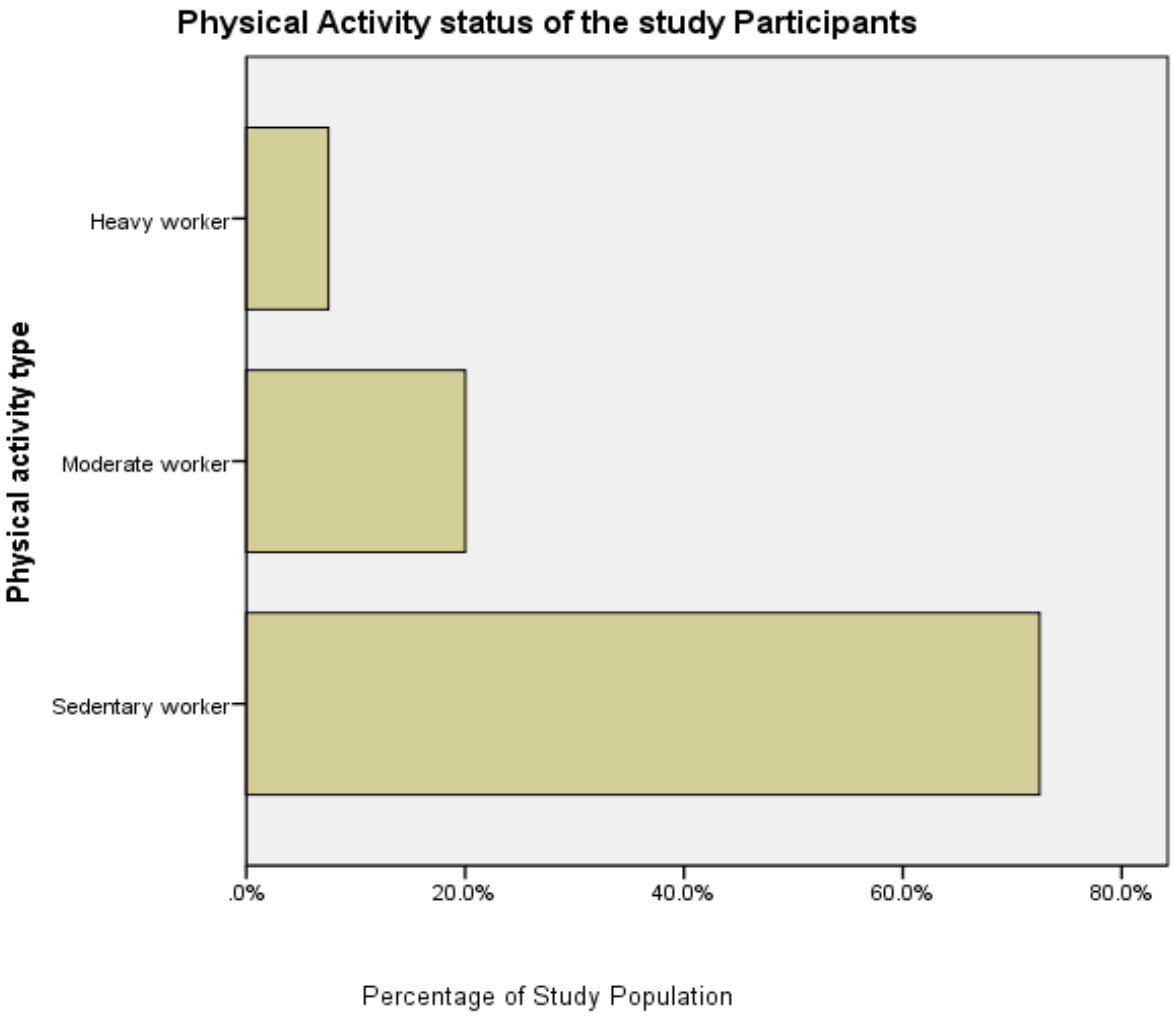


**Figure 5.2: Graph depicting the physical activity status of the study participants**

In the study population 40 ,72.5% people are sedentary,20% people are Moderate workers, whereas only 7.5% people are Heavy workers.

| Tobacco Consumption | No of study Participants(N) | Percentage(%) |
|---|---|---|
| Yes | 7 | 17.5 |
| No | 33 | 82.5 |

**Table 5.2: Tobacco Consumption**

Among the study group 17.5% having smoking habit whereas the remaining 82.5% are not smokers.

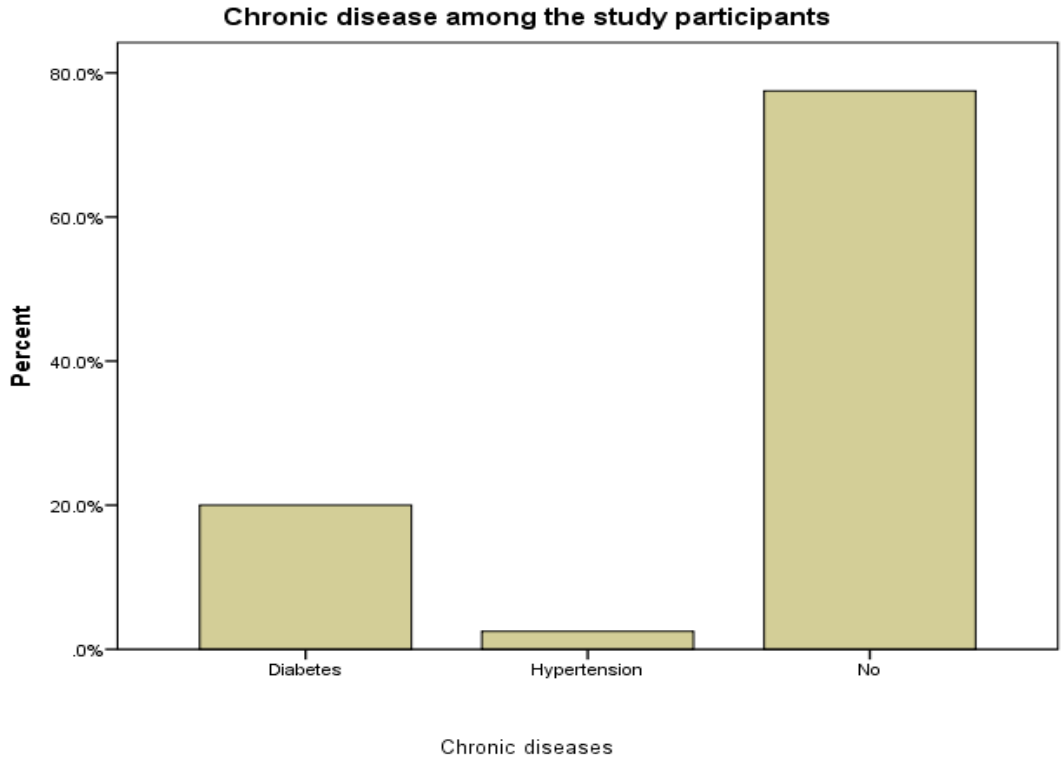


**Figure 5.3: Chronic disease among participants.**

Among the study participants 22.5% have Chronic disease and 77.5% doesn't have any disease. Out of the 22.5% having Chronic disease,20% have the Diabetes Mellitus and the 2.5% have Hypertension .

| Goniometer | Mean ±SD | Mean difference | 95% Confidence Interval of the difference | | P Value |
|---|---|---|---|---|---|
| | | | Lower | Upper | |
| Before | 80.63±6.323 | 23.5±5.335 | 25.206 | 21.794 | .0001 |
| After | 104.13±7.586 | | | | |

**Table 5.3: Mean range of motion**

The mean range of motion among the study participants measured by goniometer was 80.63 degrees before the hot affusion bath with Epsom salt and increased to 104.13 after the intervention. This difference was found to be statistically significant. p=.0001)

| WOMAC pain score | Median(IQR) | P value |
|---|---|---|
| Before | 58.8541(56.250-63.541) | .0001* |
| After | 34.375(31.25-39.0625) | |

**Table 5.4: Median for pain score**

The pain among the study participants measured by WOMAC scale was 58.85 before the hot affusion bath with Epsom salt and reduced to 34.37 after the intervention. This difference was found to be statistically significant. (p=.0001)

**Table 5.5: Association between pain reduction and baseline sociodemographic parameters:**

| Sociodemographic parameters | No of participants (N) | Percentage (%) | $X^2$ | P Value |
|---|---|---|---|---|
| Gender | | | | |
| Male | 27 | 67.5 | 8.376 | .004* |
| Female | 13 | 32.5 | | |
| Age | | | | |
| <60 | 27 | 67.5 | 3.723 | .054 |
| >60 | 13 | 32.5 | | |
| Education | | | | |
| Middle school | 37 | 92.5 | .961 | .553 |
| Higher secondary | 3 | 7.5 | | |
| Type of Toilet | | | | |
| Indian | 10 | 32.5 | 2.222 | .136 |
| Western | 30 | 67.5 | | |
| Occupation | | | | |
| Employed | 36 | 90 | 2.963 | 0.85 |
| Unemployed | 4 | 10 | | |

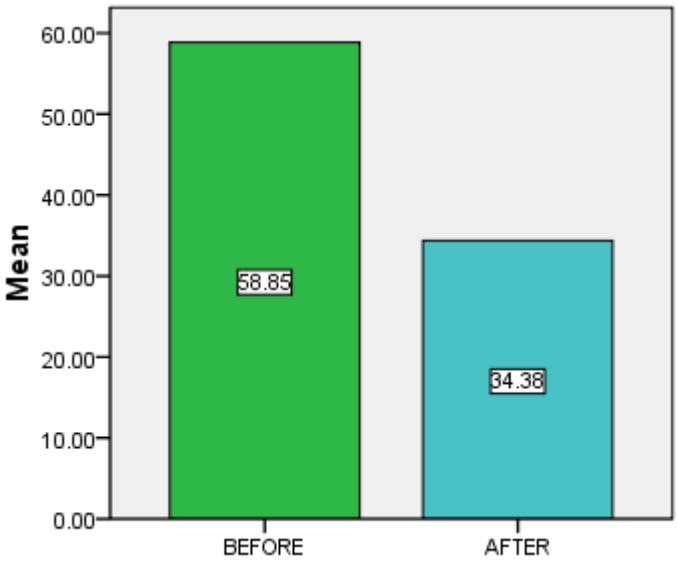


**Fig 5.4 Bar chart representing pre and post mean values of WOMAC scale**

## 6.0 DISCUSSION

The present study results shows that the Hot affusion bath(HAB) with Epsom salt at a temperature of 104º f for 15 minutes has significant improvement in reduction in knee pain, stiffness and improvement in physical motion and range of motion.

The result of the study revealed that HAB with Epsom salt show significant changes in the post test of primary and secondary outcomes.

The trial was expected to produce clinical evidence that Hot affusion bath and Epsom salt is well established for its effect in the pain relief and improve the range of motion. As the incidence is increasing mainly in this trial was conducted.

The main focus of this study was to assess the effectiveness of Hot affusion bath with Epsom salt among elderly patients with OA Knee joint pain. The research design adopted was an experimental pre-test and post-test. The population was old age patients in the age group of 50-65 years with knee joint pain. The conceptual framework of this research was based on Modified Imogene king's Goal attainment theory model.

The subjects were assessed patients global assessment (WOMAC - Western Ontario and McMaster Universities Secondary Osteoarthritis index) and range of motion(goniometry) these methods have been reported to be most satisfactory for assessing severity of pain, patients global assessment and range of motion.

In this study HAB with Epsom salt show significantly reduced values obtained after 3 week of treatment compared to that of the baseline in pain, and significant improvement in range of motion after the 3 week of intervention.

A study reported by **Ruby Anitha et al., (2015)** to assess the effectiveness of Epsom salt fomentation on knee joint pain, knee swelling and activities of daily living among elderly. It was one group pre-test post-test experimental design with 30 samples. Results reveals with significant improvement ($p<0.01$) in pain, swelling and activities of daily living after 5 days of therapy.

**Fioravanti A, Tenti S, Giannitti C, Fortunati NA, Galeazzi M.(2013)** conducted a prospective randomized , single blind controlled trial to evaluate the effectiveness of Epsom salt compress in 60 outpatients with bilateral pain divided into two groups with experimental group treated with 12 daily generalized thermal baths with magnesium sulfate and normal mineral water for control group for a duration of three months the study results confirmed that Epsom salt bath had a beneficial effect in patients with joint OA .

Thus, our study indicates that hot affusion bath with Epsom salt may reduce the body pain, stiffness and improves the range of motion. The study revealed hot affusion bath with Epsom salt reduced the pain score from $58.854 \pm 34.375$ and increased the range of movement from $80.63 \pm 6.323$ to $104.13 \pm 7.586$. Results reveals with significant improvement ($p<0.001$) in pain, swelling and activities of daily living after three weeks of treatment.

## 6.1 STRENGTH OF THE STUDY

- The recording of assessments were done during the Hot affusion bath with Epsom salt for a better understanding.
- Probably this could be the first study documented the effect of on Hot affusion bath with Epsom salt on OAK

## 6.2 IMPLICATIONS

1. For Early intervention and to prevent deformity and economic loss for individual family and country Mass screening is necessary.

2. Simple life style changes such as walking, yoga, healthy dietary habits leads the community, osteoarthritis knee joint deformity free.

3. Osteoarthritis knee joint needs further research with the therapeutic treatment in order to prevent further surgeries, so it will benefit the patient and prevent the global burden.

## 7.0 CONCLUSION:

The present study showed that Hot affusion bath with Epsom salt given thrice a week for period of 3 weeks for patient suffering from OAK shows significant improvement in subjective and objective parameters. In objective parameter WOMAC index and goniometer used, revealed significant reduction in pain and significant improvement in range of movement, in the degree of flexion. Hence, the Hot affusion bath with Epsom salt shows to be effective in patient with Osteoarthritis of knee. The study shows Significance in the physical function and range of motion to extend improves the quality of life in the elderly people of OAK. So this is a very safe and effective method of treatment as a holistic approach.

**LIMITATIONS:**

The current study was done with a minimum number of subjects with intervention given thrice a week alternatively for three weeks and further follow up was not done in the study. The outcome variable (Pain scale) used in the study is subjective one.

**RECOMMENDATIONS FOR FUTURE STUDY:**

- The same study can be conducted on a larger population and longer duration with suitable study design and some objective kind of outcome variables could be included to validate the current results.
- The hot affusion bath with Epsom salt can be used in other musculo-skeletal disease and rheumatoid arthritis and study can be done.

## 8.0 SUMMARY

Pain is defined as an unpleasant sensation occurring in varying degrees of severity as a consequence of injury, disease, or emotional disorder. It is more than unpleasant sensations. It is one of the major component part of our nervous system. Ultimately it is a perception, and a bodily state. Despite its unpleasantness, pain is acritical component of the body's defence system. Osteoarthritis (OA) is a wear and tear type arthritis. It has two primary processes; breakdown of cartilage in joints and abnormal bony growth formation called Osteophytes. It is a chronic degenerative disease that leads to structural alteration and biochemical changes of synovial membrane and joint capsule. It is of multi-factorial aetiology.

Naturopathy can be defined as a system of man building in harmony with nature cure on constructive principles on physical, mental, moral and spiritual planes of being and consist of non-invasive treatment modalities. One of the naturopathy treatment is Hydrotherapy. The internal or external use of water with various temperatures, pressure, duration, and site and different modes of application in any of its forms (water, ice, steam) for health promotion or treatment of various diseases. Among various techniques of hydrotherapy, the hot affusion bath with Epsom salt are used to treat knee pain. Attempts are being made to find the effects of hot affusion bath with Epsom salt. Hence, the present study adopts an immediate approach in comparing the effect of Hot affusion bath with Epsom salt on the Osteoarthritis of Knee.

The data were found to both normally distributed and skewed. Results were compared within the groups, whereas data was extracted at both baseline and

post -intervention. Study group showed significant improvements in WOMAC Scale of Pain index, Range of Motion, Stiffness and physical function. Hence, the immediate remedy for the pain in the Osteoarthritis and the range of motion after the Hot affusion Bath with Epsom Salts has shown a positive influence.

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## ANNEXURE - 1

## INFORMED CONSENT FORM

**Title of the study:** TO EVALUATE THE EFFECT OF HOT AFFUSION BATH WITH EPSOM SALT ON PAIN MANAGEMENT IN OSTEOARTHRITIS OF KNEE.

**Name of the Participant: _____**

**Name of the Principal Investigator:** Dr. B. Prabhakaran

**Name of the Institution:** Government Yoga & Naturopathy Medical College & Hospital, Chennai – 600 106

**Documentation of the informed consent**

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in the study titled, "TO EVALUATE THE EFFECT OF HOT AFFUSION BATH WITH EPSOM SALT ON PAIN MANAGEMENT IN OSTEOARTHRITIS OF KNEE"

1. I have read and understood this consent form and the information provided to me.

2. I have had the consent document explained to me.

3. I have been explained about the nature of the study.

4. I have been explained about my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.

6. I have been advised about the risks associated with my participation in this study.

7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.

8. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.

9. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.

10. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.

11. I have understood that my identity will be kept confidential if my data are publicly presented.

12. I have had my questions answered to my satisfaction.

13. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

**For adult participants:**

**Name and signature of the participant**

Name _____ Signature_____

Date_____

**Name and Signature of the investigator or his representative obtaining consent:**

Name _____ Signature_____

Date_____

## ANNEXURE - 2

## INFORMATION TO PARTICIPANTS

**Investigator: Dr. B. Prabhakaran**

**Name of Participant:**

**Study title: Title: "TO EVALUATE THE EFFECT OF HOT AFFUSION BATH WITH EPSOM SALT ON PAIN MANAGEMENT IN OSTEOARTHRITIS OF KNEE"**

You are invited to take part in this research study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are being asked to participate in this study being conducted in Government Yoga & Naturopathy Medical College & Hospital, Chennai – 600 106

**What is the Purpose of the Research?**

The purpose of the research study is to assess the effect of Hot Affusion Bath with Epsom Salt on pain management in Chronic Osteoarthritis of knee.

**Study Procedure:**

The experimental protocol consist of one session to be performed on separate days during morning hours during out-patient timing. Study group will be receiving Hot affusion bath with Epsom salt to knees daily for 15 minutes for 15 days(alternatively).

**Possible Risks to you:** Nil

**Possible benefits to you:** Pain will be relieved

**Confidentiality of the information obtained from you**

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors, IEC and any person or agency required by law to view your data, if required.

The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

**How will your decision to not participate in the study affect you?**

Your decisions to not to participate in this research study will not affect your treatment or your relationship with investigator or the institution.

**Can you decide to stop participating in the study once you start?**

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during course of the study without giving any reasons.

However, it is advisable that you talk to the research team prior to stopping the participation.

The results of the study may be intimated to you at the end of the study period.

Signature of investigator Signature of participant

Date:

## ANNEXURE - 3

## QUESTIONARRE

| Sl. No. | Variables | Answers |
|---|---|---|
| 1 | Subject id no: | |
| 2 | Age: | |
| 3 | Gender: 1.Male 2.Female 3.Transgender | |
| 4 | Religion: 1. Hindu 2.Christian 3.Muslim 4.Others | |
| 5 | Education: 1 .Profession or Honours 2.Graduate or Post graduate 3.Intermediate or Post high school diploma 4.High School certificates 5.Middle school certificate 6.Primary school 7.Certificate Illiterate | |
| 6 | Occupation: 1.Professional 2.Semi-Professional 3.Clerical,Shop-Owner,Farmer 4.Skilled Worker 5.Semiskilled worker 6.Unskilled worker 7.Unemployed | |
| 7 | Family Income(per month): | |
| 8 | Do you use Tobacco? 1.Yes 2.No | |
| 9 | Tobacco use pattern: 1.Smoking 2.Chewing 3.Sniffing 4.Others | |
| 10 | Do you consume alcohol: 1.Yes 2.No | |
| 11 | Menopause(women) : 1.yes 2.no | |
| 12 | Height (in cms) | |
| 13 | Weight (in kgs) | |

| | | |
|---|---|---|
| 14 | Body Mass Index (BMI) 1.Underweight 2.Normal 3.Overweight 4.Obese | |
| 15 | Any other chronic disease 1.DM 2. HTN 3. BA 4. NO | |
| 16 | Type of Physical Activity: 1.Sedentary 2.Moderate 3.Heavy | |
| 17 | Present Exercise Status:1. No Exercise 2.Low 3.Moderate 4.High | |
| 18 | Exercise status before developing Knee pain:1.No exercise 2.Low 3.Moderate 4.High | |
| 19 | Type of Toilet use:1.Indian 2.Western 3.Both | |
| 20 | Knee joint involvement:1.Right 2.Left 3.Both | |
| 21 | Knee Pain status in last 3 months:1.Present 2.Absent | |
| 22 | Current treatment of knee pain 1. Tablets 2. Injection 3. Physiotherapy 4. Others 5. No | |

ANNEXURE - 4

The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC)

Name: Date:

Instructions: Please rate the activities in each category according to the following:

scale of difficulty: 0 = None, 1 = Slight, 2 = Moderate, 3 = Very, 4 = Extremely

Circle one number for each activity

**Pain**

| | |
|---|---|
| 1. Walking | 0 1 2 3 4 |
| 2. Stair Climbing | 0 1 2 3 4 |
| 3. Nocturnal | 0 1 2 3 4 |
| 4. Rest | 0 1 2 3 4 |
| 5. Weight bearing | 0 1 2 3 4 |

**Stiffness**

| | |
|---|---|
| 1. Morning stiffness | 0 1 2 3 4 |
| 2. Stiffness occurring later in the day | 0 1 2 3 4 |

**Physical Function**

| | |
|---|---|
| 1. Descending stairs | 0 1 2 3 4 |
| 2. Ascending stairs | 0 1 2 3 4 |
| 3. Rising from sitting | 0 1 2 3 4 |

| | |
|---|---|
| 4. Standing | 0 1 2 3 4 |
| 5. Bending to floor | 0 1 2 3 4 |
| 6. Walking on flat surface | 0 1 2 3 4 |
| 7. Getting in / out of car | 0 1 2 3 4 |
| 8. Going shopping | 0 1 2 3 4 |
| 9. Putting on socks | 0 1 2 3 4 |
| 10. Lying in bed | 0 1 2 3 4 |
| 11. Taking off socks | 0 1 2 3 4 |
| 12. Rising from bed | 0 1 2 3 4 |
| 13. Getting in/out of bath | 0 1 2 3 4 |
| 14. Sitting | 0 1 2 3 4 |
| 15. Getting on/off toilet | 0 1 2 3 4 |
| 16. Heavy domestic duties | 0 1 2 3 4 |
| 17. Light domestic duties | 0 1 2 3 4 |